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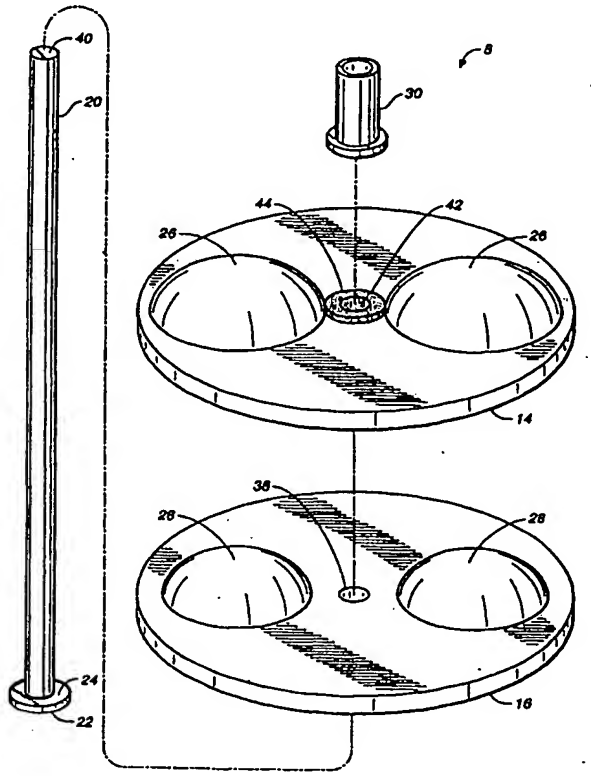
(54) Title: DEVICE FOR THE TREATMENT OF DAMAGED HEART VALVE LEAFLETS AND METHOD OF USING THE DEVICE

(57) Abstract

This invention is a device (8) and method for treating infected or damaged heart valve tissue by selectively heating, applying pressure, or both to the heart valve tissue; to sterilize any infected portion of the tissue; to reshape any misshapen portion; to effect selective thinning of any thickened portion; and to reduce the flopping of any selected portion. The heat can be applied to or induced in the heart valve tissue.



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DEVICE FOR THE TREATMENT OF DAMAGED HEART VALVE LEAFLETS AND METHOD OF USING THE DEVICE

FIELD OF THE INVENTION

The present invention is related generally to the modification of heart tissue for the treatment of damaged heart valve leaflets.

BACKGROUND OF THE INVENTION

As is well known, the heart has four chambers for receiving and pumping blood to various parts of the body. During normal operation of the heart, oxygen-poor blood returning from the body enters the right atrium. The right atrium fills with blood and eventually contracts to expel the blood through the tricuspid valve to the right ventricle. Contraction of the right ventricle ejects the blood in a pulse-like manner into the pulmonary artery and each lung. The oxygenated blood leaves the lungs through the pulmonary veins and fills the left atrium. The left atrium fills with blood and eventually contracts to expel the blood through the mitral valve to the left ventricle. Contraction of the left ventricle forces blood through the aorta to eventually deliver the oxygenated blood to the rest of the body.

There are conditions in which the heart valves (i.e., mitral valve, aortic valve, pulmonic value and tricuspid valve) do not close completely (i.e., incompetence) causing reverse flow of blood through the valve (i.e., regurgitation) resulting in a murmur as blood goes back through the valve. Often times, the valve leaflets are found to have been damaged by infection (e.g., streptococcus). The valve leaflets damaged by infection are typically thickened, especially on the edges, therefore incapable of sealing the opening across which they lie.

Other times, the valve leaflets are found to be atherosclerotic (i.e., thickened and calcified). Typical treatments for atherosclerosis include inflating a

balloon in the valve to break plaque loose from the valve and, for severe cases, valve replacement with either a mechanical or pig valve. There are some conditions in which the valve leaflets show indication of subacute bacterial endocarditis. Typically, a valve replacement procedure is conducted to treat subacute bacterial endocarditis.

Collagen-containing tissue is ubiquitous in the human body and demonstrates several unique characteristics not found in other tissues. Intermolecular cross links provide collagen-containing tissue with unique physical properties of high tensile strength and substantial elasticity. A property of collagen is that its material properties can be changed when elevated in temperature and force is applied. The molecular response to temperature elevation and force is believed to be the result of rupture of the collagen stabilizing cross links or the result of a change in the hydration of the tissue.

There has been discussion in the existing literature regarding alteration of collagen-containing tissue in different parts of the body. One known technique for effective use of this knowledge of the properties of collagen is through the use of infrared laser energy to effect tissue heating. The use of infrared laser energy as a corneal collagen shrinking tool of the eye has been described and relates to laser keratoplasty, as set forth in U.S. Patent No. 4,976,709. The importance of controlling the localization, timing and intensity of laser energy delivery is recognized as paramount in providing the desired soft tissue shrinkage affects without creating excessive damage to the surrounding non-target tissues. Another known technique of altering collagen is described in U.S. Patent No. 5,458,596 to treat joints. U.S. Patent No. 5,437,664 describes using a catheter for venous occlusion and coagulation of blood.

SUMMARY OF THE INVENTION

The present invention provides a device and method for treating damaged heart valve leaflets of a mammalian heart by heating or compressing, or both, the

valve leaflet to sterilize any infected portion of the leaflet, reshape any misshapen portion, effect selective thinning of any thickened portion, or reduce the floppiness of any selected portion.

In one aspect of the invention, there is provided an apparatus for treating an infected or damaged heart valve leaflet, having a support rod having a first end, a first member having at least one protrusion thereon and a first member opening through the first member for receiving the support rod, the first member being adjacent the first end of the support rod, a second member having at least one protrusion thereon corresponding to the protrusion on the first member and a second member opening through the second member for receiving the support rod, and means for energizing the first member and the second member to heat the infected or damaged heart valve leaflet.

In another aspect of the invention, there is provided a method for treating an infected or damaged heart valve leaflet, including the steps of placing a member in contact with the heart valve leaflet and energizing the member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

In another aspect of the invention, there is provided a method for treating an infected or damaged heart valve leaflet, including the steps of placing a first member having at least one curved surface thereon in contact with a first side of the heart valve leaflet such that the heart valve leaflet conforms to the curved surface, placing a second member having at least one curved surface thereon in contact with a second side of the heart valve leaflet such that the heart valve leaflet is in contact with the curved surface on the first member and the curved surface on the second member, and energizing the first member and the second member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

In yet another aspect of the invention, there is provided a method for

training a person to perform a method for treating an infected or damaged heart valve leaflet, including the step of demonstrating or instructing the performance of the following steps of placing a first member having at least one protrusion thereon in contact with a first side of the heart valve leaflet such that the heart valve leaflet conforms to the surface of the protrusion, placing a second member having at least one protrusion thereon in contact with a second side of the heart valve leaflet such that the heart valve leaflet is in contact with the protrusion on the first member and the protrusion on the second member, and energizing the first member and the second member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

In still another aspect of the invention, there is provided a modified mammalian heart having a heated heart valve leaflet which has been sterilized or reshaped.

In yet still another aspect of the invention, there is provided a method for treating an infected heart valve leaflet, including the step of energizing a heating element in contact with or close proximity to the infected heart valve leaflet to raise the temperature of an infected region to a temperature sufficient to sterilize the heart valve leaflet.

In another aspect of the invention, there is provided a method for training a person to perform a method for treating an infected or damaged heart valve leaflet, including the step of demonstrating or instructing the performance of the following steps of placing a member in contact with the heart valve leaflet, and energizing the member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

In another aspect of the invention, there is provided a modified mammalian heart having a compressed heart valve leaflet which has been reshaped.

BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention wherein:

FIG. 1 is an exploded perspective view of one embodiment of a device for treating damaged or infected heart valve leaflets;

FIG. 2 is a mammalian heart with a healthy heart valve;

FIG. 3 is a mammalian heart with a damaged or infected heart valve;

FIG. 4 is an enlarged diagrammatic representation partially in cross-section of a portion of the device during to treatment of the damaged valve leaflet;

FIG. 5 is another embodiment of the device in accordance with the present invention;

FIG. 6 is still another embodiment of a portion of the device in accordance with the present invention;

FIG. 7 is yet another embodiment of the device in accordance with the present invention; and

FIG. 8 is a diagrammatic representation of yet still another embodiment of the device in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a device and method for altering the material properties of collagen-containing damaged or infected heart valve tissue in a mammalian heart. There also is provided a method of training a person to perform a method for treating the damaged or infected heart valve tissue in a

mammalian heart. The invention accurately controls the inducement of heat or application of heat within a specific thermal range, and delivers thermal energy to the damaged or infected valve leaflet tissue to sterilize any infected portion of the tissue, reshape any misshapen portion, effect selective thinning of any thickened portion, or reduce the floppiness of any selected portion. The invention compresses the damaged valve leaflet tissue in some instances to reshape the leaflet. As a result, the competency of the damaged or infected heart valve is restored. Likewise, a modified mammalian heart having a heated, reshaped heart valve leaflet results.

FIG. 1 illustrates the components of the device 8 in accordance with a first embodiment of the present invention. The device 8 comprises a rod 20 having a stop plate 22 at a distal end 24 of the rod and two plates 14 and 16 for applying heat (or inducing heat in) to damaged or infected heart valve leaflets 18 and 19 (FIG. 3). The top plate 14 and bottom plate 16 have mating protrusions 26 and 28, respectively, for contacting respective surfaces of the valve leaflets 18 and 19 being treated as described below. A releasable locking member 30 is also provided to apply pressure and hold the plates 14 and 16 in compression on the valve leaflets 18 and 19 being treated, if it is desired to heat and compress the valve leaflets. Therefore, it will be appreciated that the valve leaflets can be treated with heat, compression, or both in accordance with the present invention.

Referring to FIG. 2, there is illustrated a heart 10 having a healthy heart valve 11 which is a mitral or bicuspid valve having two valve leaflets 13 and 15 which meet and close off completely during operation. The heart valve 12 of FIG. 3 is a damaged or infected mitral or bicuspid valve having two valve leaflets 18 and 19. As best seen in FIG. 3, the edges 32 and 33 of leaflets 18 and 19, respectively, are thickened and jagged due to either current or past infection or atherosclerosis. As a result, the valve 12 is incompetent such that the edges 32 of leaflet 18 do not seal with the edges 33 of leaflet 19 when the valve 12 closes. In some circumstances, leaflet 18 may have a creased portion that results in the leaflet being inverted partially from its normal convex or domed shape. The

present invention can be used to treat one or both of these conditions, if present, in the damaged or infected mitral valve 12. The present invention can be used with the tricuspid, pulmonic or aortic valves, as well, as will be discussed in more detail below.

The valve 12 of the heart 10 can be accessed with conventional open chest surgery techniques. A top plate 14 and bottom plate 16 are placed on opposite sides of the valve 12 to induce resistive heating in the heart valve tissue when energy is applied across the plates 14 and 16 (FIG. 4). The bottom plate 16 is placed below the valve 12 by a surgeon (or an individual demonstrating) by inserting the distal end 24 of the rod 20 through the opening 36 between the valve leaflets 18 and 19, then placing the bottom plate 16 onto the rod 20 through the opening 38 in the bottom plate 16. (Likewise, an individual can instruct a surgeon on how to accomplish the method of the present invention with the device 8 or other embodiments disclosed herein.) The bottom plate 16 is pushed down on the rod 20 and worked through the opening 36 between the valve leaflets 18 and 19. The bottom plate 16 rests in contact with the stop plate 22 at the distal end 24 of the rod 20. The rod 20 is pulled back up slightly until the protrusions 28 on bottom plate 16 contact the bottom surfaces of each of the valve leaflets (only one shown in FIG. 4). The protrusion 28 on the bottom plate 16 pushes up on valve leaflet 18 to return the leaflet to its normal convex or domed shape. Top plate 14 is placed above the valve 12 by inserting the proximal end 40 of the rod 20 through the opening 42 in the top plate 14. The top plate 14 is pushed down on the rod 20 into contact with the top surface of each of the valve leaflets. The concave portion of the protrusions 26 on top plate 14 mate with the convex portion of the protrusions 28 on bottom plate 16. The top plate 14 is electrically insulated from the rod 20 by insulating disk 44. A negative electrode 46 is attached to the proximal end 40 of the rod 20. The bottom plate 14 is in electrical communication with the rod 20. A positive electrode 48 is attached to the top plate 14 such that the top plate 14 and bottom plate 16 operate as electrodes. The positive and negative electrodes 48 and 46 are then energized by the surgeon to function as a heating element. As the electrodes are energized the temperature of

the tissue in the desired valve leaflet 18 and/or 19 is raised to a temperature sufficient to sterilize or reshape the valve leaflet(s) without ablating the tissue or damaging the healthy tissue surrounding the valve 12. The term "heating element" as used herein encompasses elements that apply energy thereby inducing heat in the tissue as well as to elements that apply heat to the tissue. In a preferred embodiment, the tissue is heated to a temperature in the range of about 40 degrees Celsius to about 110 degrees Celsius, more preferably about 60 degrees Celsius to about 65 degrees Celsius.

If compression is needed for treatment, either with or without heat, a releasable locking member 30 (FIGS. 1 and 4) is pushed down on the rod 20 into contact with the top plate 14 to apply pressure to the valve leaflets 18 and 19 located between the convex portion of the protrusions 28 on bottom plate 16 and the concave portion of the protrusions 26 on the top plate 14 (FIG. 4). The amount of applied pressure depends on the condition of the valve leaflet. Typically, the applied pressure is between 1 and 50 pounds per square inch. The releasable locking member 30 is electrically insulated from the rod 20 and the top plate 14. After the desired treatment area has been heated (and compressed if needed), it is allowed to cool. Energy is no longer applied after there has been sufficient sterilization or reshaping of the valve tissue to restore valve competency. Likewise, pressure is no longer applied after there has been sufficient reshaping of the valve tissue to restore valve competency if no heating is needed. Sufficient sterilization or reshaping may be detected visually, mechanically, or with appropriate feed back variables, such as temperature monitoring, or any other suitable method.

The convex portion of the protrusions 28 on bottom plate 16 and the concave portion of the protrusions 26 on the top plate 14 are shaped to contact the valve leaflets 18 and 19 in a desired manner so that the valve leaflets 18 and 19 are thinned and smoothed out at the edges 32 and 33, respectively, to restore competency to the heart valve 12. The convexity and concavity of the protrusions 26 and 28, along with the temperature and/or pressure, control the reshaping of

the valve leaflets. As can be seen in FIG. 7, an alternate embodiment of top plate 14 and bottom plate 16 can have protrusions 50, bumps, scales, ridges, grooves, indentations, or the like on their respective surfaces that contact the valve leaflets to prevent movement of the leaflets. A series of differently shaped and/or sized protrusions and plates can be used to treat the valve leaflets 18 and 19 incrementally until the desired shape or competency is reached.

Some examples of different plates are shown in FIGS. 5 and 6. In FIG. 5, the top plate 114 and bottom plate 116 are basically only one-half of the top plate 14 and bottom plate 16 shown in FIG. 1. In this way, the rod 20 and bottom plate 116 can be more easily inserted through the valve 12. The top plate 114 and bottom plate 116 are used to treat either valve leaflet 18 or 19 whichever may be infected or damaged. If both leaflets are damaged, one leaflet can be treated first then the top plate 114 and bottom plate 116 can be rotated to treat the other leaflet. As will be evident to one of ordinary skill in the art, a tricuspid valve can be treated with the top plate 114 and bottom plate 116 of FIG. 5 by treating each infected or damaged valve leaflet in the tricuspid valve separately. In FIG. 6, there is shown a bottom plate 216 having three protrusions 28 for treating a tricuspid valve (not shown) in combination with a top plate (not shown) having three protrusions (not shown) for mating with the protrusions 28 on plate 216.

The device 8 illustrated in the figures utilizes resistive heating of the valve tissue, but it is also within the scope of the invention that other means can be utilized. The method is contemplated to be used with any suitable appliance for applying radiant energy, thermal energy, or to otherwise heat the infected or damaged tissue. For example, a radio-frequency generator connected to the top plate 14 and 16 in a bipolar manner (diagrammatically similar to the resistive heating embodiment) can be used. A unipolar configuration can be used as well. An outer electrode (not shown) having a much larger surface area than the plates 14 and 16 is placed on the outer surface of the patient's body. For example, an external metal mesh or solid plate is placed on the skin. Both the plates and the outer electrode are connected to radio-frequency generator which produces an

electric field at a high frequency within the patient's body. Because the surface area between the plates 14 and 16 is much smaller than the surface area of the outer electrode, the density of the high frequency electric field is much higher between the plates. The electric field reaches its highest density between the plates. The increased density of the field between the plates produces localized heating of the valve leaflet tissue. In either embodiment, when the top plate 14 and 16 are positioned at the desired treatment site, the radio-frequency generator is activated to provide suitable energy, preferably at a selected frequency in the range of 10 megahertz to 1000 megahertz, to heat the leaflet tissue to a temperature sufficient to sterilize or reshape the leaflet tissue without damaging the healthy tissue surrounding the heart valve 12. Preferably, the emitted energy is converted within the leaflet tissue into heat in the range of about 40 degrees Celsius to about 110 degrees Celsius, more preferably in the range of about 60 degrees Celsius to about 65 degrees Celsius and in the range of about 100 degrees Celsius to about 110 degrees Celsius for sterilization. The radio-frequency energy is preferably applied at low power levels (e.g., 1 to 20 watts/cm^2). Suitable radio-frequency power sources are readily commercially available. In one embodiment, the radio-frequency generator has a single channel, delivering approximately 1 to 20 watts/cm^2 of energy and possessing continuous delivery capability.

FIG. 8 is a diagrammatic representation of another embodiment of the present invention wherein the top plate 14 and bottom plate 16 are heated with a light source 66, for example, a laser or halogen source. The light source 66 transmits light via fiber optic light pipe 68 to lens 70 which diffuses the light onto parabolic heat sink 72 to convert the light energy to heat that is conducted through the rod 20 to the top plate 14 and bottom 16.

The heating element of any of the embodiments can be made to provide protection against overheating of the valve tissue. Techniques, for example temperature monitoring or electrical characteristic monitoring (e.g., impedance), can be utilized in a system which shuts down the application of energy to the heating element to avoid ablating the tissue or damaging healthy tissue. The

surgeon can, if desired, override the feedback control system. A microprocessor can be included and incorporated into the feedback control system to switch the power on and off, as well as modulate the power. The microprocessor can serve as a controller to watch the temperature and modulate the power in order to avoid over-heating of the tissue. Furthermore, the system can include auditory or visual feedback indicators for signalling when reshaping, heating, temperature, or other variables are occurring and also when any have reached or exceeded desired conditions.

It is to be understood that other forms of energy, in addition to those discussed above and diagrammatically similar as those discussed, such as light, microwaves, ultrasound, and the like can be used to apply or induce heat in the desired tissue, and that the thermal energy generated from a hot fluid element (e.g., liquids, gases, combinations of liquids and gases, etc.), a curie point element, or similar elements can be used as well. The plates in accordance with any of the embodiments can be a number of different materials including but not limited to conductive polymer, stainless steel, platinum, or other noble metals.

While several particular embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is Claimed is:

1. An apparatus for treating an infected or damaged heart valve leaflet, comprising:

a support rod having a first end;

a first member having at least one protrusion thereon and a first member opening through the first member for receiving the support rod, the first member being adjacent the first end of the support rod;

a second member having at least one protrusion thereon corresponding to the protrusion on the first member and a second member opening through the second member for receiving the support rod; and

means for energizing the first member and the second member to heat the infected or damaged heart valve leaflet.

2. The apparatus of Claim 1 wherein the first member and the second member comprise electrodes for heating the heart valve leaflet.

3. The apparatus of Claim 1 wherein the means for energizing comprises a radio-frequency generator.

4. The apparatus of Claim 1 wherein the means for energizing comprises microwave means for heating the heart valve leaflet.

5. The apparatus of Claim 1 wherein the means for energizing comprises ultrasound means for heating the heart valve leaflet.

6. The apparatus of Claim 1 wherein the means for energizing comprises light means for heating the heart valve leaflet.

7. The apparatus of Claim 1 wherein the means for energizing comprises a hot fluid element.

8. The apparatus of Claim 1 further comprising a feedback indicator.

9. The apparatus of Claim 8 wherein the feedback indicator is an auditory signal.

10. The apparatus of Claim 8 wherein the feedback indicator is a visual signal.

11. The apparatus of Claim 8 wherein the feedback indicator is indicative of temperature.

12. The apparatus of Claim 8 wherein the feedback indicator is indicative of electrical characteristics.

13. The apparatus of Claim 1 further comprising a member for applying pressure with the first member and the second member to the heart valve leaflet.

14. The apparatus of Claim 1 wherein the first member has a plurality of protrusions thereon and the second member has a plurality of protrusions thereon corresponding to the plurality of protrusions on the first member.

15. The apparatus of Claim 1 wherein the protrusion on the first member has a plurality of protrusions or indentations thereon.

16. A method for treating an infected or damaged heart valve leaflet, comprising the steps of:

placing a member in contact with the heart valve leaflet; and

energizing the member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

17. The method of Claim 16 wherein the member is energized by applying radio-frequency energy.

18. The method of Claim 16 wherein the member is energized by resistive heating.

19. The method of Claim 16 wherein the heart valve leaflet is energized to a temperature in the range of about 40 degrees Celsius to about 110 degrees Celsius.

20. The method of Claim 16 further comprising:

placing a second member in contact with an opposite side of the heart valve leaflet so that the heart valve leaflet is between the oppositely disposed members.

21. The method of Claim 20 further comprising:

compressing the heart valve leaflet between the oppositely disposed members.

22. A method for treating an infected or damaged heart valve leaflet, comprising the steps of:

placing a first member having at least one curved surface thereon in contact with a first side of the heart valve leaflet such that the heart valve leaflet conforms to the curved surface;

placing a second member having at least one curved surface thereon in contact with a second side of the heart valve leaflet such that the heart valve leaflet is in contact with the curved surface on the first member and the curved surface on the second member; and

energizing the first member and the second member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

23. The method of Claim 22, further comprising the step of:

compressing the heart valve leaflet between the first member and the second member.

24. The method of Claim 22 wherein the heart valve leaflet is energized to a temperature in the range of about 40 degrees Celsius to about 110 degrees Celsius.

25. A method for training a person to perform a method for treating an infected or damaged heart valve leaflet, comprising the step of:

demonstrating or instructing the performance of the following steps of:

placing a first member having at least one protrusion thereon in contact with a first side of the heart valve leaflet such that the heart valve leaflet conforms to the surface of the protrusion;

placing a second member having at least one protrusion thereon in contact with a second side of the heart valve leaflet such that the heart valve leaflet is in contact with the protrusion on the first member and the protrusion on the second member; and

energizing the first member and the second member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

26. The method of Claim 25 further comprising the step of:

demonstrating or instructing the performance of the following step of:

compressing the heart valve leaflet between the first member and the second member.

27. A modified mammalian heart having a heated heart valve leaflet which has been sterilized or reshaped.

28. A method for treating an infected heart valve leaflet, comprising the step of:

energizing a heating element in contact with or close proximity to the infected heart valve leaflet to raise the temperature of an infected region to a temperature sufficient to sterilize the heart valve leaflet.

29. A method for training a person to perform a method for treating an infected or damaged heart valve leaflet, comprising the step of:

demonstrating or instructing the performance of the following steps:

placing a member in contact with the heart valve leaflet; and

energizing the member to heat the heart valve leaflet to a temperature sufficient to sterilize or reshape the heart valve leaflet.

30. The method of Claim 29 further comprising the step of:

demonstrating or instructing the performance of the following step of:

placing a second member in contact with an opposite side of the heart valve leaflet so that the heart valve leaflet is between the oppositely disposed members.

31. The method of Claim 30 further comprising the step of:

demonstrating or instructing the performance of the following step of:

compressing the heart valve leaflet between the oppositely disposed members.

32. A modified mammalian heart having a compressed heart valve leaflet which has been reshaped.

33. A modified mammalian heart of Claim 32 wherein the heart valve leaflet has been heated.

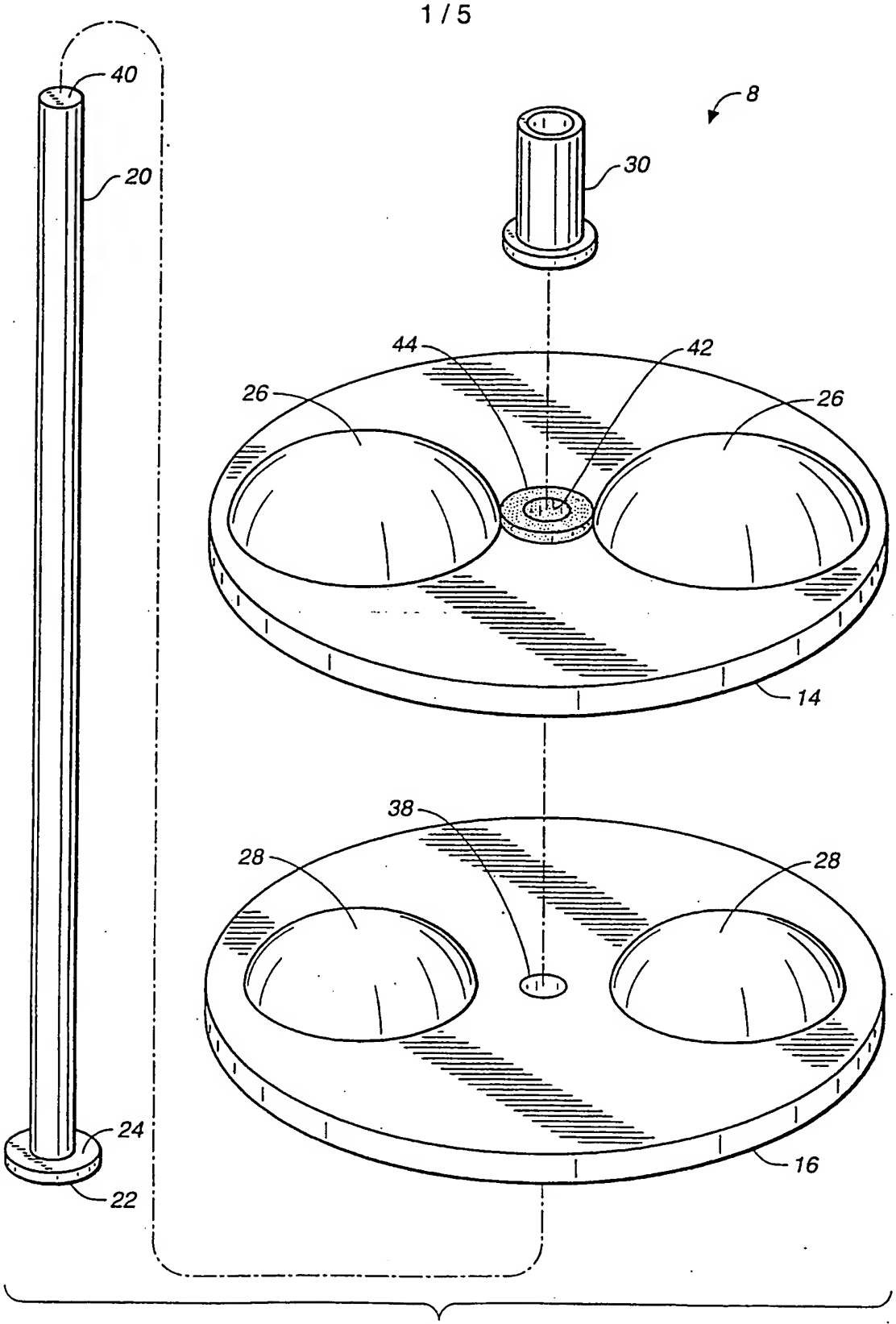

FIG._1

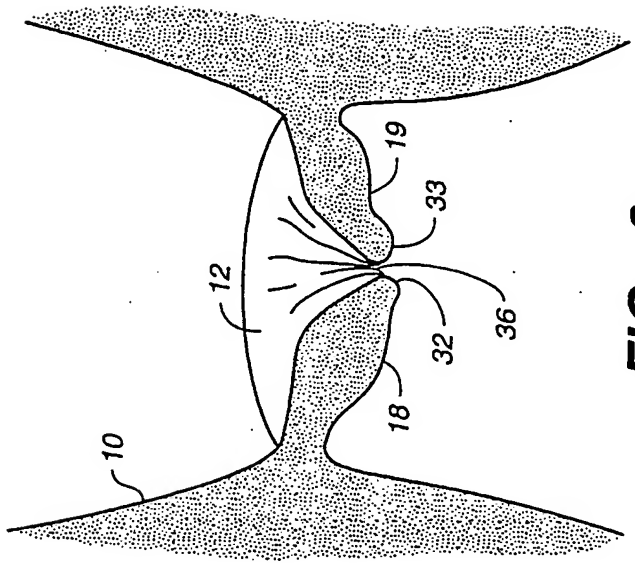

FIG._3

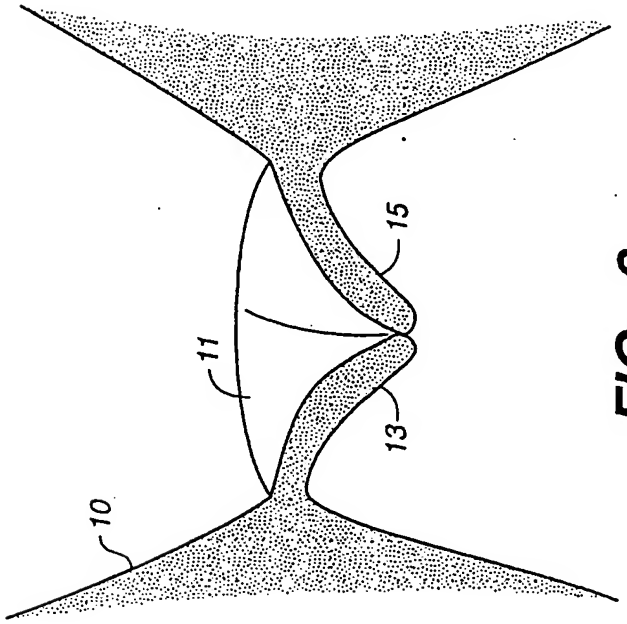

FIG._2

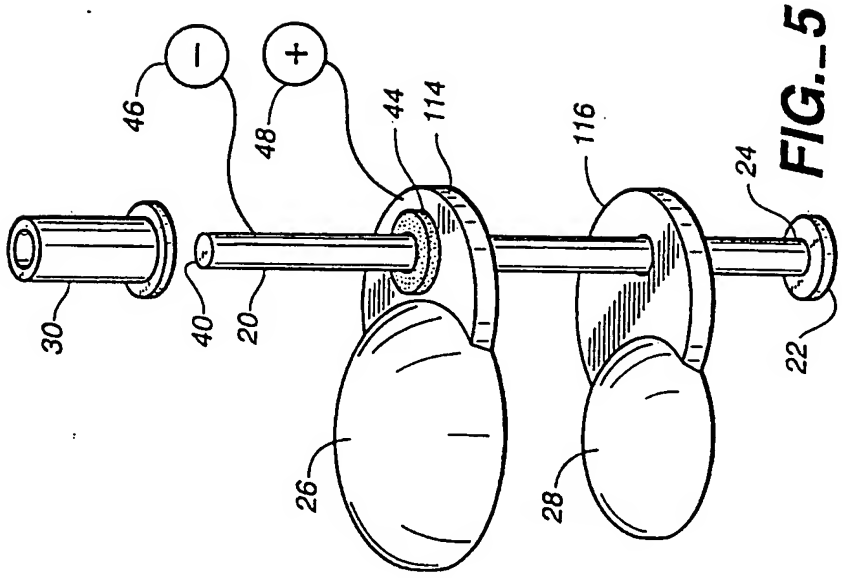
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FIG._5

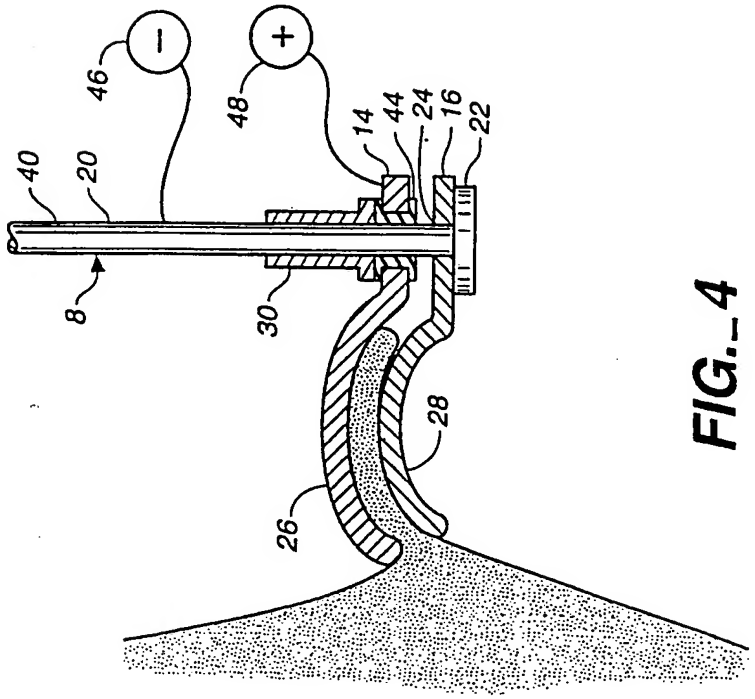
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FIG._4

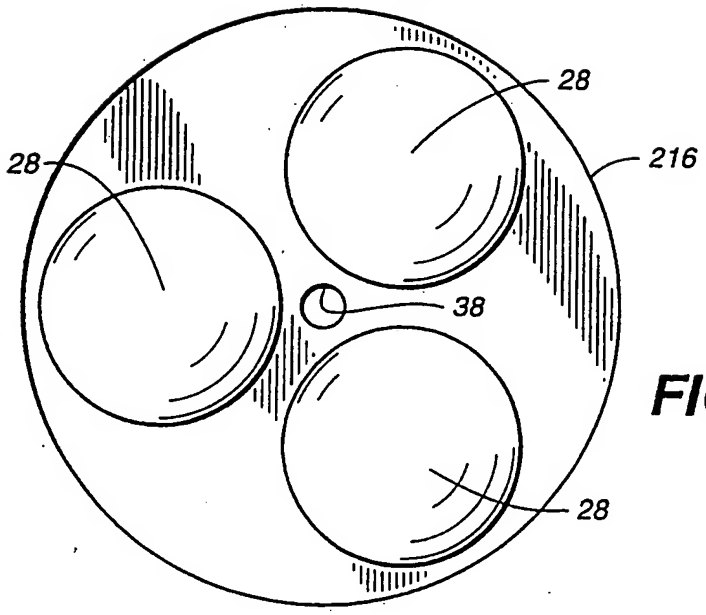

FIG._6

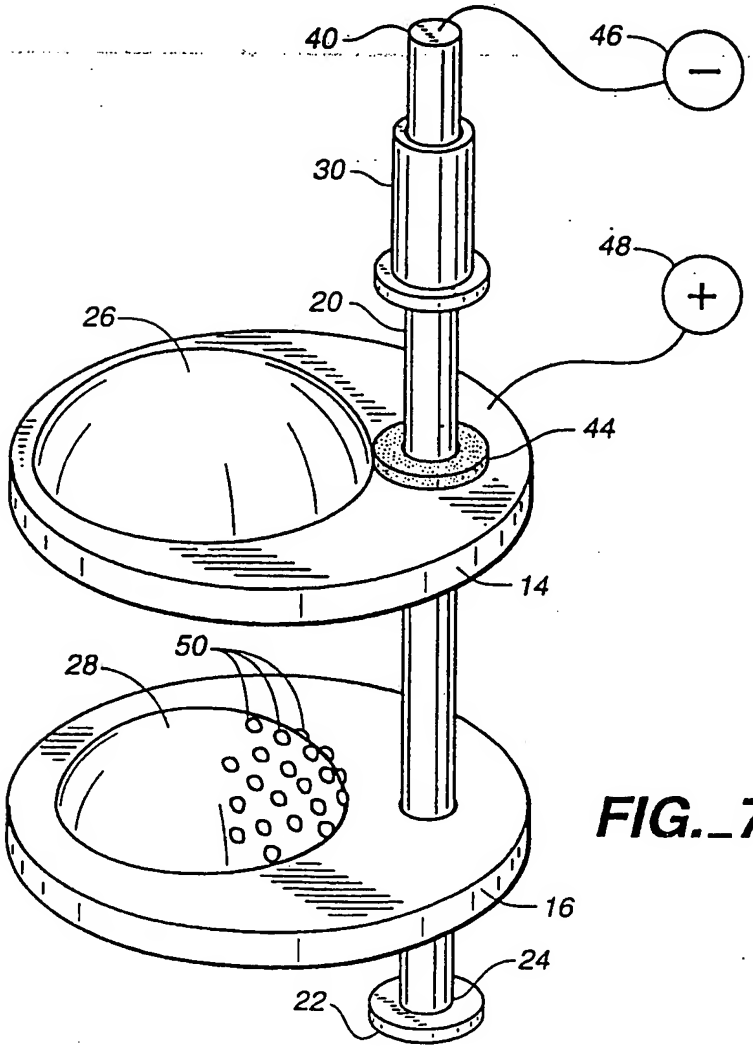

FIG._7

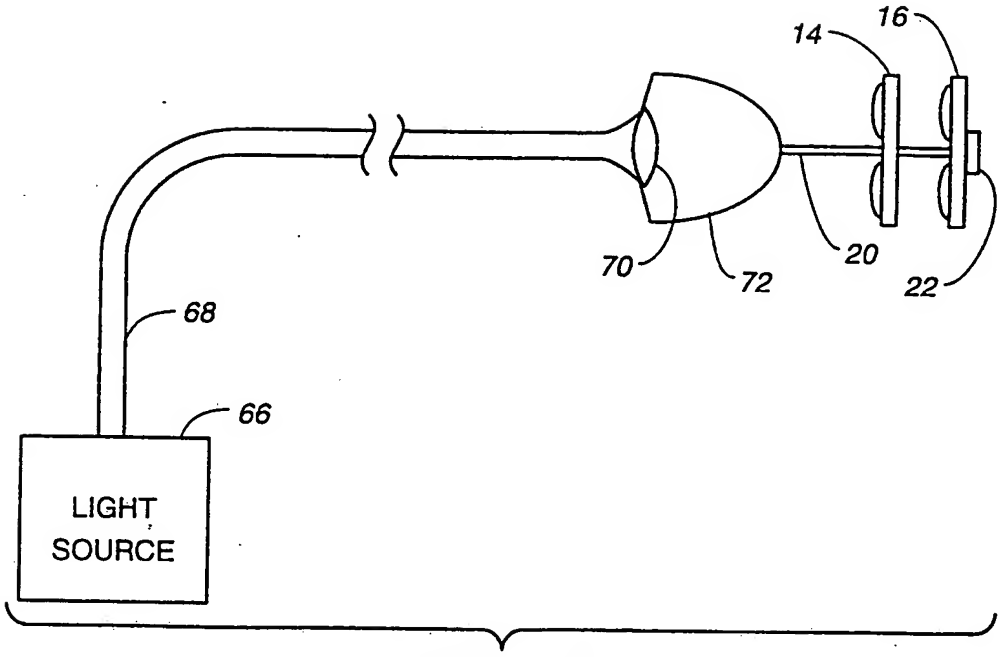

FIG._8

INTERNATIONAL SEARCH REPORT

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PCT/US97/24013

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 17/36
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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/41-46, 48, 50, 52

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 5,217,460 A (KNOEPFLER) 08 June 1993, whole document	1-4, 13-15 — 5-12, 16-33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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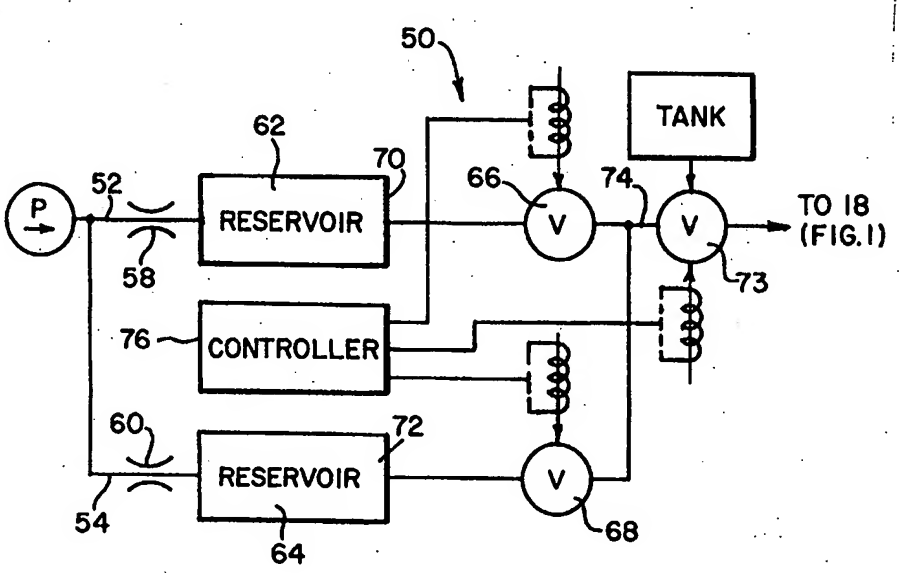
(54) Title: DRIVE SYSTEM FOR CONTROLLING CARDIAC COMPRESSION



(57) Abstract

This invention is an inflation system (50) for independently controlling the pressure profile, namely the rise time and plateau level of fluid supplied to an inflatable chamber (18) by a fluid source (56) by means of fluid passages (52, 54) leading to high and low pressure regulators (58, 60), and tanks (62, 64) whose outputs are controlled by valves (66, 68) to provide the required high and low pressures at specific times to define the pressure profile.

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DRIVE SYSTEM FOR CONTROLLING CARDIAC COMPRESSION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to systems for mechanically assisting the heart and more particularly to a drive system capable of controlling the rise time and plateau level of a pressure pulse applied to a cardiac compression apparatus.

2. Discussion of the Related Art

Heart disease accounts for one of the leading causes of cardiac dysfunction among individuals worldwide. One of the more common heart disorders often associated with heart disease involves substantial weakening of the heart. Left unaided, a critically weakened heart often cannot pump the necessary blood required to sustain bodily functions.

An important life-saving technique for individuals diagnosed with weakened hearts includes mechanically assisting the heart to pump blood. Such support ensures an adequate blood pressure for sufficiently supplying blood throughout the body without undue stress on the heart muscle. Typically, a device such as a heart compression apparatus carries out the assistance during invasive surgery. An alternative device incorporating cardiopulmonary resuscitation (CPR) techniques externally compresses the chest to rhythmically squeeze the heart area and assist in increasing blood flow.

Those skilled in the art have proposed a variety of devices to successfully carry out the heart compression function to maximize support for the heart and provide reliable and accurate functionality. One such device, disclosed in pending Provisional U.S. Patent Application Serial Number 60/028,722, filed on October 18, 1996 and assigned to the assignee of the present invention, carries and supports the heart during invasive surgery while uniformly applying pressure directly to the heart through means of an inflatable liner. The liner is cyclically inflated and deflated by an inflation system to apply pressure to the heart.

Because each heart pumps blood according to a pressure profile unique for each patient, successful cardiac compression on the inflatable liner depends upon the inflation system being controllable to somewhat match the patient's personal cardiac rhythm or pressure profile. An important consideration is the sharp rise in ventricular pressure during the early portion of systole, which provides only about fifty to one hundred milliseconds within which to establish synchronous compression.

One conventional inflation system for controlling the rise time and plateau level of a pressure pulse utilizes a single regulator-reservoir configuration. The system includes a compressor connected to a regulator, and a reservoir disposed downstream of the regulator. An outflow valve connects to the reservoir outlet and is placed in fluid communication with an inflation chamber disposed in a cardiac compression apparatus for supporting and assisting a heart. During operation, the compressor supplies flow through the regulator, which maintains a desired pressure in the tank. Inflation of the chamber occurs by opening the outflow valve to produce an exponentially increasing pressure transient within the chamber that asymptotically approaches the supply pressure level to define a relatively constant pressure, or plateau level, within a known response time.

While this system works relatively well to ensure that the pressure applied to the liner never exceeds the supply pressure, the configuration provides a relatively accurate adjustment of the plateau level without any independent control over changes in the rise time of the start transient. Generally, the waveforms may

be expressed as:

$$P = P_{PLATEAU} * [1 - \exp(-t/T)]$$

wherein t represents time, and T represents the system time constant. As illustrated in Fig. 3, regardless of the plateau setting, the time constant T remains unchanged with changes only in the magnitude of the plateau level. Because of this characteristic, control of the rise time using the conventional inflation system is generally possible only by affecting the system resistances, capacitances, or source regulator pressure. As a result, the response of the transient to reach the plateau level is typically of the order of three time constants. The rise time, known commonly as the time required to reach the plateau level, generally depends upon system characteristics such as overall resistance and capacitance. Therefore, having the capability of merely controlling the plateau level does not enable independent control over the rise time.

Moreover, because of the controlled conditions associated with surgical environments, the conventional inflation system is often disposed several feet from the inflation chamber. As a result, a relatively long hose generally couples the inflation system to the compression apparatus liner. Coupled with the effects of overall system resistances and pressure load, the resulting time constant realized by the conventional inflation system substantially degrades system performance. Alternatively, should the resistance be lowered through expansion of the tubing diameter, the size, weight and cost for the components required to effect a larger flowrate would render the system undesirable from a practical standpoint.

A second proposal solves several of the aforementioned problems by implementing a source pressure substantially higher than the desired plateau pressure. The pressure circuit is similar to the first proposal described above, but includes an additional control valve disposed in series with the outflow valve. Operation of the system depends upon precise timing to initially open both valves simultaneously, exposing the liner to an exponentially increasing pressure characteristic of the source pressure level, then closing the control valve upon

reaching a desired plateau pressure and trapping the pressure within the liner for a timed duration.

While this proposal is somewhat beneficial in offering a way of controlling the rise time independently of the desired plateau pressure, the precise timing required to effectively control the plateau level by closing the control valve at precisely the right instant is difficult in practice to achieve. This is typically due to the equilibrium time required from the instant the valve closes until the plateau pressure is actually realized. As a result, the system often exhibits an undesirable overshoot or undershoot of the plateau pressure causing an unexpected deviation in the cardiac compression apparatus liner.

Therefore, those skilled in the art have recognized the need for an inflation system capable of following a predefined pressure profile with independent control of both rise time and plateau level with a minimum number of components and accurate repeatability. The inflation system of the present invention satisfies these needs.

SUMMARY OF THE INVENTION

The inflation system of the present invention provides a straightforward means of inflating a cardiac compression apparatus according to a predefined pressure profile and having an independently controllable rise time and plateau level. Additionally, the system incorporates a minimum number of components to minimize size and associated procurement and operating costs.

To realize the advantages noted above, the inflation system of the present invention, according to a first embodiment, independently controls the rise time and plateau level of a pressure cycle profile applied to an inflatable chamber. In one form, the invention includes a pneumatic source for pressurizing fluid at a predetermined pressure and a pressure path disposed in fluid communication with the source. The pressure path includes a regulation device for establishing respective high and low pressure levels. A supply mechanism disposed at the output of the pressure path is operative to alternately expose the chamber to the high and

low pressure levels according to predetermined switchable durations to define the rise time and plateau levels.

In another form, the present invention comprises a heart assistance system for supporting and assisting the cyclic pumping of a heart. The heart assistance system includes a cardiac compression apparatus having a support cup and an internal inflation chamber for uniformly compressing the heart. An inflation system applies a pressure pulse to the inflation chamber and places the heart in cyclic compression by independently controlling the rise time and the plateau level of the pressure pulse. The inflation system includes a pneumatic source for pressurizing fluid at a predetermined pressure and a pressure path disposed in fluid communication with the source. The pressure path includes a regulation device for establishing respective high and low pressure levels. A supply mechanism disposed at the output of the pressure path is operative to alternately expose the chamber to the high and low pressure levels according to predetermined switchable durations to define the rise time and plateau levels.

In yet another form, the invention comprises a method of independently controlling the rise time and the plateau level of a pressure cycle applied to an inflatable chamber. The method includes the steps of exposing the chamber to a first pressure from a pressure reservoir to exponentially increase the pressure within the chamber for a controllable duration defining the rise time; and switching the pressure in the reservoir following expiration of the duration to a constant second pressure defining the plateau level.

In still yet another form, the present invention includes a source pressure substantially higher than the desired plateau pressure. The pressure circuit includes two outlet lines from the tank. One outlet line has a switching valve that switches between a first regulated high pressure line and a second regulated plateau pressure line. The second output line is connected to the compression apparatus liner through a supply valve. Operation of the system depends upon precise timing of the switching valve to, first, expose the liner to the high pressure level which is greater than the plateau pressure level, then switching the valve upon reaching a

desired predetermined percentage of the plateau pressure, thereby fluidly connecting the liner to the plateau pressure. The supply valve is then switched to close (to vent the liner to atmosphere) at the end of the systolic cycle.

Other features and advantages of the present invention will be apparent from the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a non-limiting example of a cardiac assistance apparatus aiding a heart to illustrate an important application for the inflation system of the present invention;

FIGS. 2A and 2B are block diagrams of a conventional inflation system;

FIGS. 3A and 3B are timing diagrams for the conventional inflation system of Figs. 2A and 2B, respectively;

FIG. 4 is a graphical representation of an undesirable response for the conventional inflation system of Fig. 2B;

FIG. 5 is a block diagram of an inflation system according to a first embodiment of the present invention;

FIG. 6 is a timing diagram for the inflation system of Fig. 5 illustrated with respect to a portion of a pressure profile;

FIG. 7 is a block diagram of an inflation system according to a second embodiment of the present invention;

FIG. 8. is a timing diagram for the inflation system of Fig. 7 illustrated with respect to a portion of a pressure profile;

FIG. 9 is a block diagram of an inflation system according to a third embodiment of the present invention;

FIG. 10 is a timing diagram for the inflation system of Fig. 9 illustrated with respect to a portion of a pressure profile;

FIG. 11 is a block diagram of an inflation system according to a

fourth embodiment of the present invention; and,

FIG. 12 is a timing diagram for the inflation system of Fig. 11 illustrated with respect to a portion of a pressure profile.

DETAILED DESCRIPTION OF THE INVENTION

The inflation system of the present invention independently controls the rise time and plateau level of a pressure profile by switching between first and second pressure levels with a minimum number of components. The control of the rise time and plateau level is important to provide a satisfactory response time to properly match the pressure pulses of a mechanical heart assistance system with the natural pulses of the pumping heart.

By way of example, Figure 1 illustrates a cardiac compression apparatus 12 for assisting a heart 13 to pump blood through a vasculature by substantially uniformly compressing the heart ventricle during the systolic phase. An example of such an apparatus is disclosed in pending U.S. Patent Application Serial No. 60/028,722, filed on October 18, 1996, the disclosure of which is hereby incorporated by reference. The heart is placed into the apparatus which is lined with an internal inflation chamber or liner 16 that includes a port 18 for connecting to an inflation system according to the present invention.

Referring now to Figs. 2A and 3A, a first conventional inflation system for generating a pressure profile in synchronous relation with the pumping heart 13, and generally designated 34, includes a pneumatic compressor 36 having an output coupled to a regulator 38, and a reservoir or tank 40 disposed downstream of the regulator. A first control valve 43 connects to the reservoir outlet. Control valve 43 is a two-way valve and has its output directed to the inflation chamber disposed in the cardiac compression apparatus 12 of the type shown in Fig. 1. A controller (not shown) controls the actuation of control valve 43 according to relatively precise timing such as that illustrated in Fig. 3A. During operation of the first conventional inflation system, the compressor supplies flow through the regulator, which maintains a desired pressure in the tank. Inflation of

the liner 16 occurs by opening the first control valve 43 to produce an asymptotically increasing pressure transient within the chamber. The source pressure maintained within tank 40 is the desired plateau pressure. Once a predetermined duration has expired, control valve 43 is switched so that inflatable chamber port 19 of apparatus 12 is now in fluid communication with reservoir 44. Chamber 44 is simply a vent to atmosphere.

Referring now to Figs. 2B and 3B, a second conventional inflation system for generating a pressure profile in synchronous relation with the pumping heart 13, and generally designated 34, includes a pneumatic compressor 36 having an output coupled to a regulator 38, and a reservoir or tank 40 disposed downstream of the regulator. A first control valve 42 connects to the reservoir outlet. A three-way two position distribution valve 43 is placed in downstream fluid communication with the first control valve and has its output directed to the inflation chamber disposed in the cardiac compression apparatus 12 of the type shown in Fig. 1. A controller (not shown) controls actuation of the control valves 42 and 43 according to relatively precise timing such as that illustrated in Fig. 3B.

During operation of the second conventional inflation system, the compressor supplies flow through the regulator, which maintains a desired pressure in the tank. Inflation of the liner 16 occurs by simultaneously opening both the first control valve 42 and the distribution valve 43 to produce an asymptotically increasing pressure transient within the chamber. Once a predetermined duration has expired, calculated to take into account the time required for any equilibrium effects, the control valve 42 is closed while the pressure circuit traps the pressurized gas in the liner. Following a predetermined period corresponding to the duration of the systolic cycle, the distribution valve is actuated to vent the liner to atmosphere.

Fig. 4 illustrates the effect of a slight inaccuracy of the aforedescribed timing resulting in an undesirable overshoot of the desired plateau level. Such effects are often undesirable in cardiac compression applications due to higher pressure applied to the heart than are desired and, additionally, unexpected stresses

placed upon the inflatable liner 16.

Referring now to Fig. 5, the inflation system according to a first embodiment of the present invention and generally designated 50, provides the capability of independently controlling the rise time and plateau level of an applied pressure pulse. The system includes a pair of pressure paths 52 and 54 disposed in parallel fluid communication with a pneumatic source 56. The pneumatic source 56 typically comprises a controllable compressor or pump capable of producing pressurized gas at pressures between the range of 6 psi to 60 psi (300 to 3000 mmHg). An additional source suitable for this application includes a pressurized pneumatic cylinder with appropriate plumbing to step down the bottled pressure or pressure from gas distribution lines frequently supplied in hospitals to a controllable level.

The pressure paths 52 and 54 include respective regulators 58 and 60 disposed downstream of the pressure source 56 and connected to respective tanks or reservoirs 62 and 64. The regulators are configured to maintain respective high and low pressure levels within the tanks. The high pressure level is typically set within the range of approximately 150 to 300 mmHg while the low range often approximates 60 to 150 mmHg. Respective control valves 66 and 68 together comprise a supply mechanism and are disposed at the tank outlets 70 and 72 and plumbed into a common supply manifold 74. The manifold connects to the a venting mechanism 73. Venting mechanism 73 is preferably a 3-way valve with manifold 74 and the conduit from tank 75 being the inputs and the conduit lending to the inflatable chamber port 18 (Fig. 1) being the output. Tank 75 may be open to a atmosphere or to a negative pressure (i.e., a vacuum). For safety considerations, venting mechanism 73 preferably defaults to being in communication with the inlet conduit from tank 75.

A controller 76 electrically connects to the solenoids of the respective control valves 66 and 68 to sequence the valve states according to a predetermined timing scheme illustrated in Figure 6.

Operation of the inflation system 50 involves activating a control

signal 77 (Fig. 6) to open the high pressure supply control valve 66 and opening the valve 73 to manifold 74 to pressurize the inflatable chamber 16 according to a higher magnitude transient characteristic of the predetermined high pressure. At the end of a predetermined duration, corresponding to the rise time of the pressure profile, a second control signal 78 closes the high pressure supply valve 66 while simultaneously signaling the low pressure supply valve 68 to open. The regulating action of the low pressure path quickly zeroes in the chamber pressure to that of the desired plateau pressure 79.

At the end of the systolic phase, the controller 76 returns the chamber to its pre-pressurized condition by deactivating and closing the low pressure supply control valve 68 and quickly relieving the system with venting mechanism 73 to atmospheric pressure to approximate the release phase of the heart pressure profile. The entire cycle repeats within a relatively short period approximating the range 400 to 1000 milliseconds to correspond with the cyclic activity of the heart.

With reference to Fig. 7, a variation of the present invention according to a second embodiment and generally designated 80, conveniently reduces the number of components necessary to implement the invention. Like the first embodiment illustrated in Fig. 5, the variation includes respective high and low pressure paths 82 and 84 driven by a single compressor P and including respective reservoirs 81 and 83, and respective regulators 85 and 87. However, unlike the aforedescribed embodiment, the outputs of the tanks terminate in a single switching valve 86 that comprises a supply mechanism and includes a solenoid actuator 88 responsive to a controller 89 to switch the valve output 90 between respective high and low pressure inputs 92 and 94. Output 90 connects to a venting mechanism 101 for introducing pressure from output 90 or atmospheric pressure from tank 103 into the inflatable chamber 16 (Fig. 1). Tank 103 may be open to atmosphere or to a negative pressure. Switching valve 86 and venting mechanism valve 101 together comprise a supply mechanism.

Referring now to Fig. 8, in the timing scheme utilized to actuate the system 80, the switching valve 86 is expected to be initially set with the low

pressure path 84 open through the output 90. Initiation of the pressure profile then begins by actuating the venting mechanism 101 with signal 97 and the switching valve 86 with signal 98, to expose the chamber to the set high pressure. Following a pre-set duration corresponding to the profile rise time, the output of the switching valve 86 switches, with signal 99, back to the normally open position thereby introducing pressurized gas from the low pressure path 84 into the chamber to settle on the pre-set low pressure level corresponding to the plateau level 93. Following the pre-set desired duration for the plateau level, a venting mechanism 101 is actuated by the controller to quickly relieve the system corresponding to the release phase of the heart profile.

Referring now to Fig. 9, the number of components necessary to carry out the general principles of the present invention may be further minimized in accordance with a third embodiment of the present invention, generally designated 100. The system includes a pneumatic source 102 for pressurizing a reservoir 104 having a supply mechanism 106 and a relief mechanism 120.

Pneumatic source 102 implemented in the third embodiment of the present invention typically comprises a controllable compressor or pump capable of producing pressurized gas at pressures between the range of 60 to 300 mmHg. An additional source suitable for this application includes a pressurized pneumatic cylinder with appropriate plumbing to step down the bottled pressure to a controllable level. Alternatively, pressurized gas that is frequently supplied by hospitals, in the form of gas distribution lines, may be used as the pressure source.

The pneumatic source 102 connects to the tank or reservoir 104 disposed in fluid communication with the supply mechanism 106 and the relief or bypass mechanism 120. The supply mechanism 106 typically comprises a three-way control valve responsive to activation of a solenoid actuator 108, which actuation is controlled by control unit 122. The output of three-way control valve 106 is connected to a pressure output 110, which is connected to the inflatable chamber port 18 (Figure 1). The input to control valve 106 is either connected to

tank 104 or to tank 105. Tank 105 may be open to atmosphere or connected to a negative (i.e., a vacuum) pressure to assist in deflating the liner during the diastolic phase. Bypass mechanism 120 typically comprises a back pressure regulator 114 connected to a bypass port on the reservoir and a control valve 116 responsive to a solenoid 118 and positioned at the regulator outlet 120.

The respective control valve solenoids 108 and 118 electrically connect and are responsive to a controller 122 that sends respective control signals 124 and 126 to the control valves according to a predefined timing scheme, shown in Figure 10. The timing scheme, in concert with the pressure levels, conveniently enables independent control of the rise time and the plateau level with a single tank and regulator.

Further referring to Figs. 9 and 10, during operation of the inflation system 100, the controller 122 initiates the start control signal 126 to open valve 116 (i.e., in fluid communication with tank 104) and close valve 106 (i.e., in fluid communication with tank 105). Valve 116 is preferably set so that when it is open, the pressure within tank 104 is at the plateau pressure ("$P_{plateau}$"). By merely changing regulator's 114 setpoint, the plateau level can be easily controllable to a relatively high degree of precision. When valves 116 and 106 are closed, tank 104 is essentially at the supply pressure of source 102 ("P_{supply}"). While still maintaining valve 106 closed, valve 116 is closed causing the pressure within tank 104 to reach P_{supply}, which is greater than $P_{plateau}$. Controller 122 opens the supply valve 106 and exposes the line 110 connected to the interior of chamber 18 (Figure 1) to pressurized gas in the range of 150 to 500 mmHg, which is equal to P_{supply}. Simultaneously, or after a short delay of between approximately 10 milliseconds to 100 milliseconds, valve 116 is opened by control signal 126 to cause the pressure within chamber 18 to approach $P_{plateau}$, without any overshoot. The pressure within chamber 18 increases exponentially toward P_{supply}, until the second control signal 126 is sent by the controller to open the control valve solenoid 118. The timed duration between the control signals corresponds to the rise time of the pressure profile. Those skilled in the art will recognize the convenient adjustability of the

compressor pressure and the timed duration to vary the rise time as necessary to closely approximate the corresponding natural rise time of the systolic cycle of the heart.

At the end of the systolic phase, the controller 122 returns the chamber to its pre-pressurized condition by deactivating and closing the supply control valve 106 and quickly venting the system to atmospheric pressure, thereby releasing the pressure in the chamber. The entire cycle repeats within a relatively short period, typically within approximately 400 to 1000 milliseconds, corresponding to the cyclic activity of the heart.

With reference to Fig. 11, another variation of the present invention according to a fourth embodiment, and generally designated as 160, is illustrated. In this embodiment, only one reservoir 142 is required. The output of pressure source 140 is in direct fluid communication with reservoir 142. A first bypass output path places tank 142 in fluid communication with either a first high pressure path 152 or a second low pressure path 154 through three-way switching valve 148. Regulators 144, 146 are connected to paths 152, 154, respectively. Regulator 144 sets the pressure within line 152 at a predetermined pressure above the plateau pressure. Regulator 146 sets the pressure within line 154 at the plateau pressure. A single switching valve 148 is connected to the inputs of fluid lines 152, 154, respectively. A controller 162 switches valve 148 so that tank 142 is either in fluid communication with high pressure line 152 or plateau pressure line 154.

A second output line 150 fluidly connects the output of tank 142 to a supply mechanism or valve 156. Supply valve 156 is similar to supply valve 106 illustrated in Fig. 9. Thus, valve 156 is a three-way valve. The input to control valve 156 is either connected to tank 142 or tank 164. Tank 164 may be open to a atmosphere or to a negative pressure.

Referring now to Figures 11 and 12, during operation of the inflation system 160, controller 162 initiates a start control signal 166 to switch valve 148 so that it is in fluid communication with high pressure line 152. Thereafter, control signal 122 initiates start control signal 168 to open supply valve 156 so that the

liner is in fluid communication with tank 142 via output line 150. Simultaneously, or after a short delay of between approximately 10 milliseconds to 100 milliseconds, controller 162 initiates a signal to switch valve 148 so that tank 142 is now in fluid communication with plateau line 154. Thus, the pressure within tank 142 will be immediately adjusted to the plateau pressure so that the pressure within chamber 18 approaches $P_{plateau}$, without any over shoot. As illustrated in Figure 12, the pressure within chamber 18 exponentially rises towards the pressure set within high pressure line 152, until a signal is sent by the controller to switch valve 148 so that the tank is now in fluid communication with the plateau pressure line 154. Those skilled in the art will recognize that while the rise to the high pressure as illustrated by ramped portion 170 in the pressure profile of Figure 12, is essentially exponential, this line is practically a straight line because of the relatively high setting of the high pressure within line 152. At the end of this diastolic phase, the controller 162 returns the chamber to its prepressurized position by switching supply valve 156 and quickly venting chamber 18 to either atmospheric pressure or to a negative pressure, as desired.

While the aforedescribed embodiments of the present invention are illustrated with respect to an independently controllable rise time for a pressure profile, it will be understood that the invention is applicable to controlling rise times for a variety of diagnostic waveforms indicating cardiac parameters with respect to time, including for example compression or force profiles.

Those skilled in the art will appreciate the many advantages afforded by the inflation system of the present invention. Of particular significance is the capability of independently controlling the rise time and plateau level of the pressure profile. With this feature, the pressure pulse can be customized to substantially match a patient's pressure profile to place the system in a more synchronous rhythm with the natural cyclic pumping of the heart. As a result, instances of destructive interference between the assistance apparatus and the heart itself are minimized, thereby maximizing the effective assistance provided to the heart.

The present invention also provides the benefit of incorporating a straightforward design to carry out the functionality with a minimum number of

mechanical components. By minimizing the number of components, costs involved in the purchase and operation of the system are dramatically reduced. Moreover, minimizing the number of mechanical components also serves to reduce the overall size and complexity of the inflation system, making the system highly desirable for portable applications. Because of the relatively few high maintenance components and corresponding plumbing lines, system reliability is substantially improved.

While the invention has been particularly shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An inflation system for independently controlling the rise time and plateau level of a pressure cycle profile applied to an inflatable chamber, said system including:

a pneumatic source for pressurizing fluid at a predetermined pressure;

a pressure path disposed in fluid communication with said source and including a regulation device for establishing respective high and low pressure levels; and

a supply mechanism disposed at the output of said pressure path and operative to alternately expose said chamber to said high and low pressure levels according to predetermined switchable durations to define said rise time and plateau levels.

2. An inflation system according to claim 1 wherein:

said pneumatic source comprises an air compressor.

3. An inflation system according to claim 1 wherein:

said pneumatic source comprises a pre-pressurized pneumatic cylinder.

4. An inflation system according to claim 1 wherein:

said pneumatic source comprises a pump.

5. An inflation system according to claim 1 wherein:

said pneumatic source comprises a pneumatic distribution line.

6. An inflation system according to claim 1 wherein:

said predetermined high pressure level is within the range 150 to 300 mmHg; and

said low pressure level is within the range 60 to 150 mmHg.

7. An inflation system according to claim 1 wherein:

said pressure path comprises

a reservoir having an inlet disposed in fluid communication with said pneumatic source and

a controllable bypass mechanism disposed in fluid communication with said reservoir and operative, when said duration expires, to controllably relieve the pressure in said reservoir to a second pressure defining said plateau level.

8. An inflation system according to claim 7 wherein:

said reservoir comprises a tank; and

said supply mechanism comprises a supply control valve disposed downstream of said tank.

9. An inflation system according to claim 7 wherein:

said bypass mechanism comprises a regulator having an inlet connected to said reservoir, and a bypass control valve connected to the outlet of said regulator.

10. An inflation system according to claim 9 and further including:

a controller for generating predefined sequenced signals to control said supply mechanism and said bypass control valve.

11. An inflation system according to claim 10 wherein:

said controller produces respective first and second signals according to timing defined by said switchable durations,

said supply mechanism operates responsive to said first signal to expose said chamber to said predetermined pressure according to an essentially exponential pressure increase; and

said bypass mechanism operates responsive to said second signal to

relieve said chamber pressure to said plateau level.

12. An inflation system according to claim 1 wherein:

said pressure path includes

a high pressure path connected to said pneumatic source and including a high pressure reservoir and a regulator to maintain a first pressure in said reservoir; and

a low pressure path connected to said pneumatic source and disposed in parallel relationship with said high pressure path and having a low pressure reservoir and a low pressure regulator to maintain a second pressure in said reservoir.

13. An inflation system according to claim 12 further comprising:

a switching valve including a first inlet and a second inlet connected to said high and low pressure paths, respectively, and an outlet connected to said chamber and operative to switch between said first and second pressure paths to selectively control the pressure within said chamber to correspondingly control said rise time and plateau level.

14. An inflation system according to claim 13 and further including:

a controller for generating predefined sequenced signals to control said switching valve.

15. An inflation system according to claim 14 wherein:

said controller produces respective first and second signals according to timing defined by said switchable durations; and

said switching valve operates responsive to said first signal to open said high pressure path and expose said chamber to said first pressure according to an essentially exponential pressure increase and responsive to said second signal to

close said high pressure path and simultaneously open said low pressure path to expose said chamber pressure to said second pressure.

16. An inflation system according to claim 13, further comprising:

a tank being in fluid communication with one of an atmospheric pressure and a negative pressure, said tank having an outlet;

a venting mechanism including a first inlet and a second inlet end connected to said outlet of said switching valve and to said outlet of said tank, respectively, said venting mechanism including an outlet connected to said chamber.

17. An inflation system according to claim 16, wherein

said venting mechanism defaults to being in fluid communication with said outlet of said tank.

18. An inflation system according to claim 12 wherein:

said high pressure level is within the range 150 to 300 mmHg; and

said low pressure level is within the range 60 to 150 mmHg.

19. An inflation system according to claim 12, further comprising:

a first control valve connected to said high pressure path and a second control valve connected to said low pressure path; and

an outlet of said first control valve and an outlet of said second control valve each being in communication with a common supply manifold.

20. An inflation system according to claim 19, further comprising:

a tank being in fluid communication with one of an atmospheric pressure and a negative pressure, said tank having an outlet;

a venting mechanism including a first inlet and a second inlet connected to said manifold and to said outlet of said tank, respectively, said venting

mechanism including an outlet connected to said chamber.

21. An inflation system according to claim 20, wherein said venting mechanism defaults to be in fluid communication with said outlet of said tank.

22. An inflation system for independently controlling the rise time and plateau level of a pressure cycle profile applied to an inflatable chamber, said system including:

a pneumatic source for pressurizing fluid at a predetermined pressure;

a pressure path disposed in fluid communication with said source and including a regulation device for establishing respective high and low pressure levels;

a reservoir having an inlet disposed in fluid communication with said pneumatic source;

a controllable switching valve disposed in fluid communication with said reservoir and operative when said duration expires, to controllably relieve the pressure in said reservoir to a second pressure defining said plateau level; and

a supply mechanism disposed at the output of said pressure path and operative to alternately expose said chamber to said high and low pressure levels according to predetermined switchable durations to define said rise time and plateau levels.

23. An inflation system according to claim 22 wherein:

said reservoir comprises a tank; and

said supply mechanism comprises a supply control valve disposed downstream of said tank.

24. An inflation system according to claim 22, wherein said switching valve comprises a three-way valve having a first inlet being a first

pressure path that is regulated to said high pressure level and a second inlet that is connected to a second pressure path that is regulated to said low pressure level and an outlet that is connected to said reservoir.

25. An inflation system according to claim 24, further including a controller for generating predefined sequence signals to control said supply mechanism and said switching valve.

26. An inflation system according to claim 25, said controller produces respective first and second signals according to timing defined by said switchable durations,

said supply mechanism operates responsive to said first signal to expose said chamber to said predetermined pressure according to an essentially exponential pressure increase; and

said switching valve operates responsive to said second signal to relieve said chamber pressure to said plateau level.

27. A heart assistance system for supporting and assisting the cyclic pumping of a heart, said compression system including:

a cardiac compression apparatus having a support cup and an internal inflation chamber for uniformly compressing said heart; and

an inflation system for applying a pressure pulse to said inflation chamber and place said heart in cyclic compression by independently controlling the rise time and the plateau level of a pressure pulse, said inflation system including

a pneumatic source for pressurizing fluid at a predetermined pressure;

a pressure path disposed in fluid communication with said source and including a regulation device for establishing respective high and low pressure levels; and

a supply mechanism disposed at the output of said pressure path

and operative to alternately expose said chamber to said high and low pressure levels according to predetermined switchable durations to define said rise time and plateau levels.

28. A method of independently controlling the rise time and the plateau level of a pressure cycle applied to an inflatable liner disposed in a cardiac compression apparatus, said method including the steps of:

exposing said liner to a first pressure from a pressure reservoir to essentially exponential increase the pressure within said liner for a controllable duration defining said rise time;

switching the pressure in said reservoir following expiration of said duration to a constant second pressure defining said plateau level.

29. A method according to claim 27 wherein:

said switching step includes relieving the pressure in said reservoir with a bypass mechanism comprising a regulator disposed in fluid communication with said reservoir, and a control valve connected to the output of said regulator.

30. A method of assisting the pumping of a heart, said pumping corresponding to a definable systolic cycle, said method including the steps of:

selecting a cardiac compression apparatus having a support cup and an inflatable liner;

exposing said liner to a first pressure from a pressure reservoir to exponentially increase the pressure within said liner for a controllable duration defining said rise time;

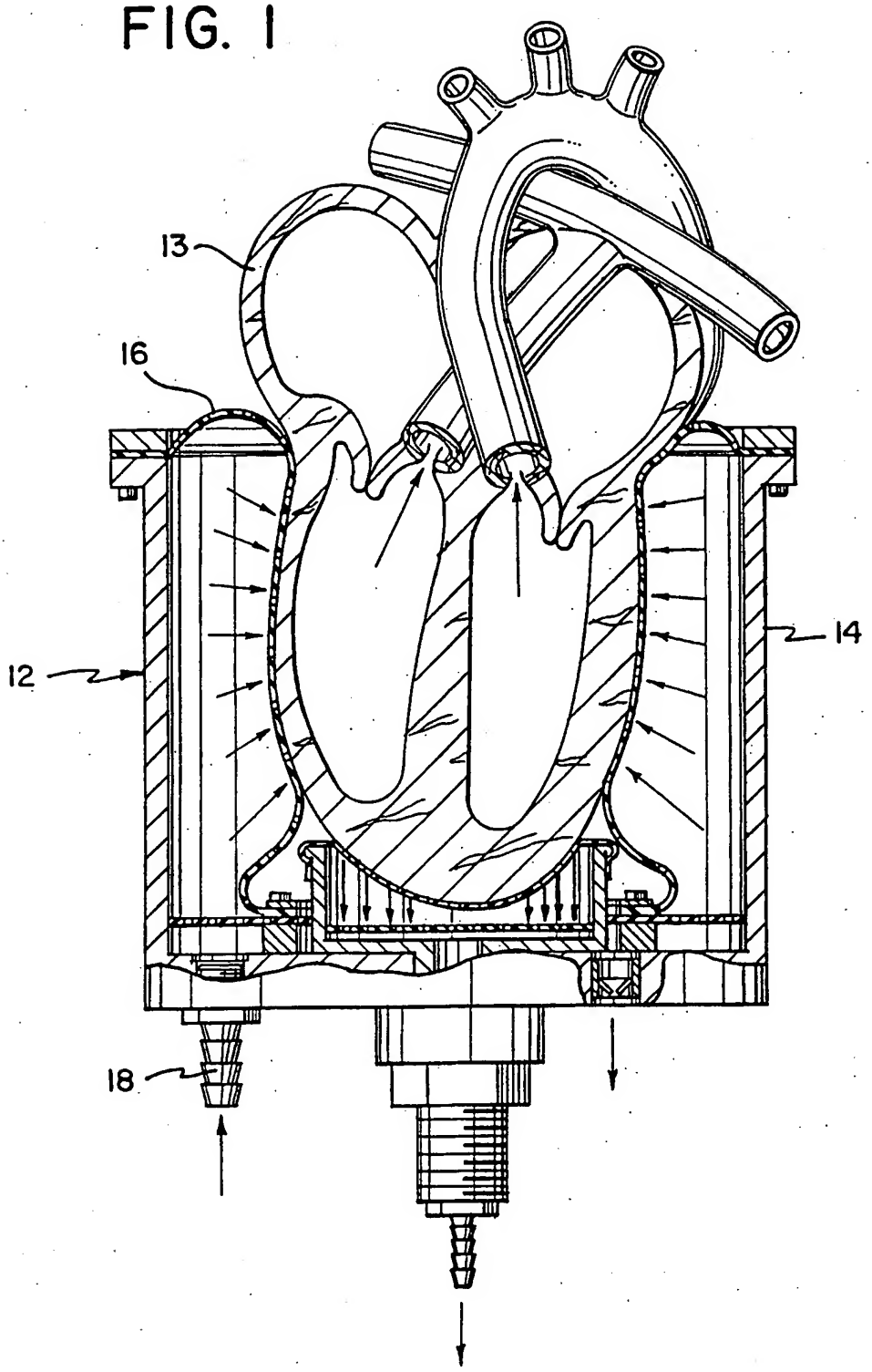
switching the pressure in said reservoir following expiration of said duration to a constant second pressure defining said plateau level.

31. A method according to claim 30 wherein:

said selecting step includes providing an inflation system having a

pneumatic source for pressurizing fluid at a predetermined pressure; a pressure path disposed in fluid communication with said source and including a regulation device for establishing respective high and low pressure levels; and a supply mechanism disposed at the output of said pressure path and operative to alternately expose said chamber to said high and low pressure levels according to predetermined switchable durations to define said rise time and plateau levels.

FIG. 1



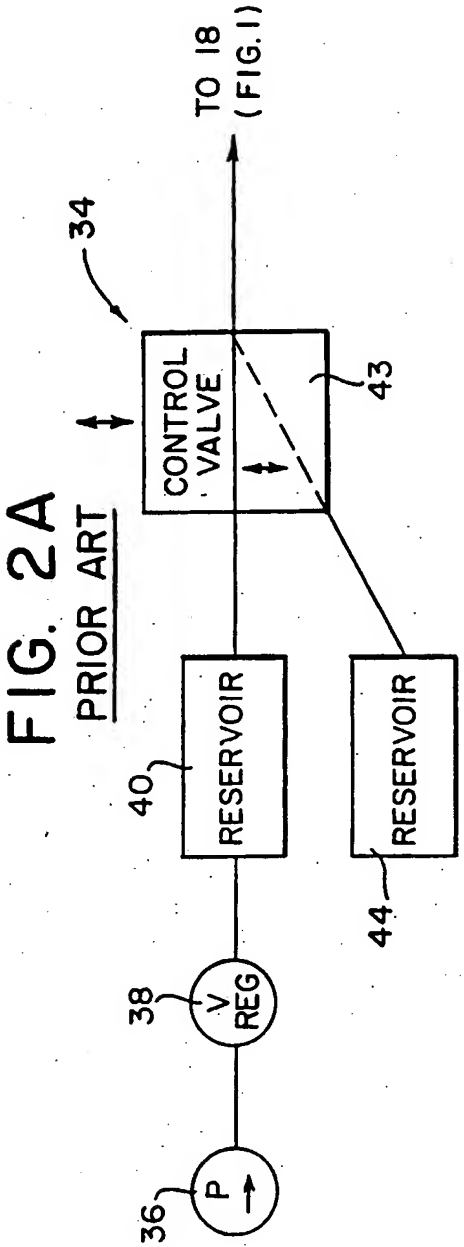


FIG. 2A
PRIOR ART

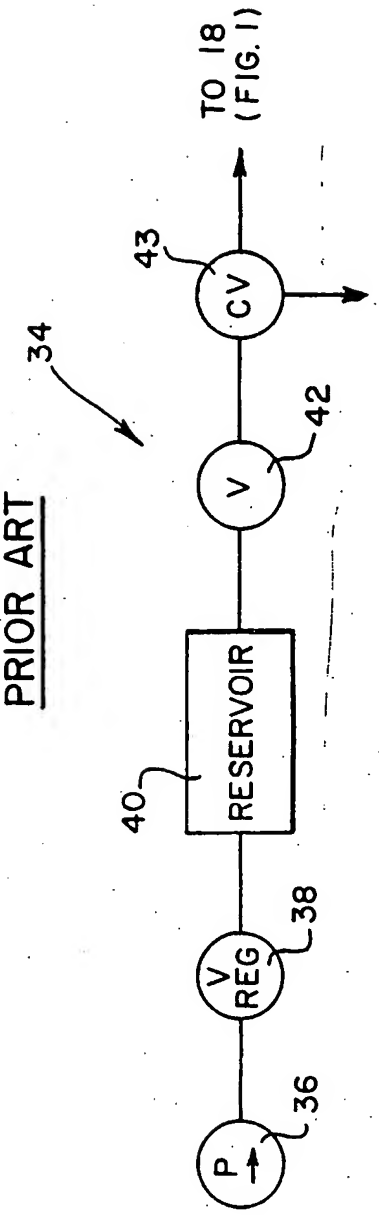


FIG. 2B
PRIOR ART

FIG. 3A
PRIOR ART

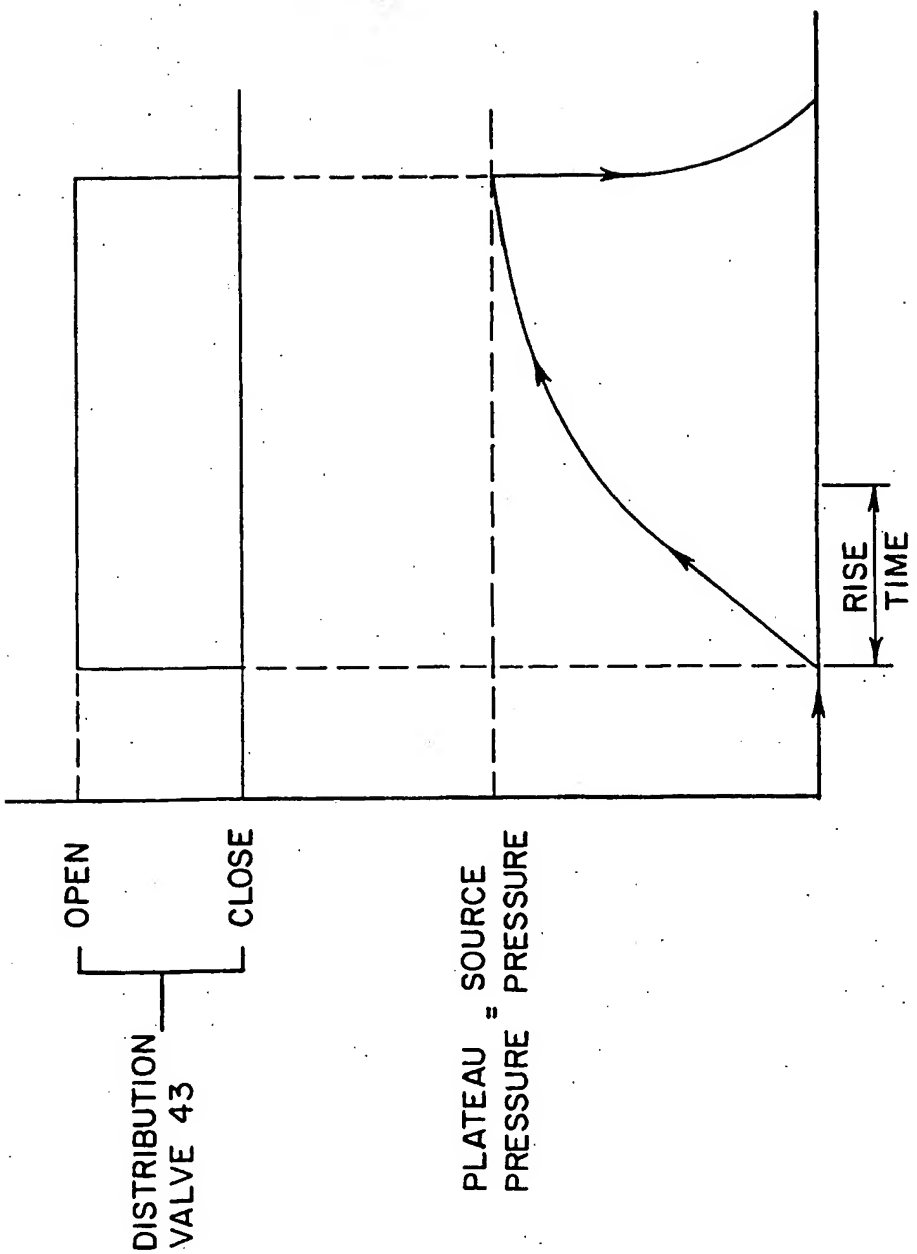


FIG. 3B
PRIOR ART

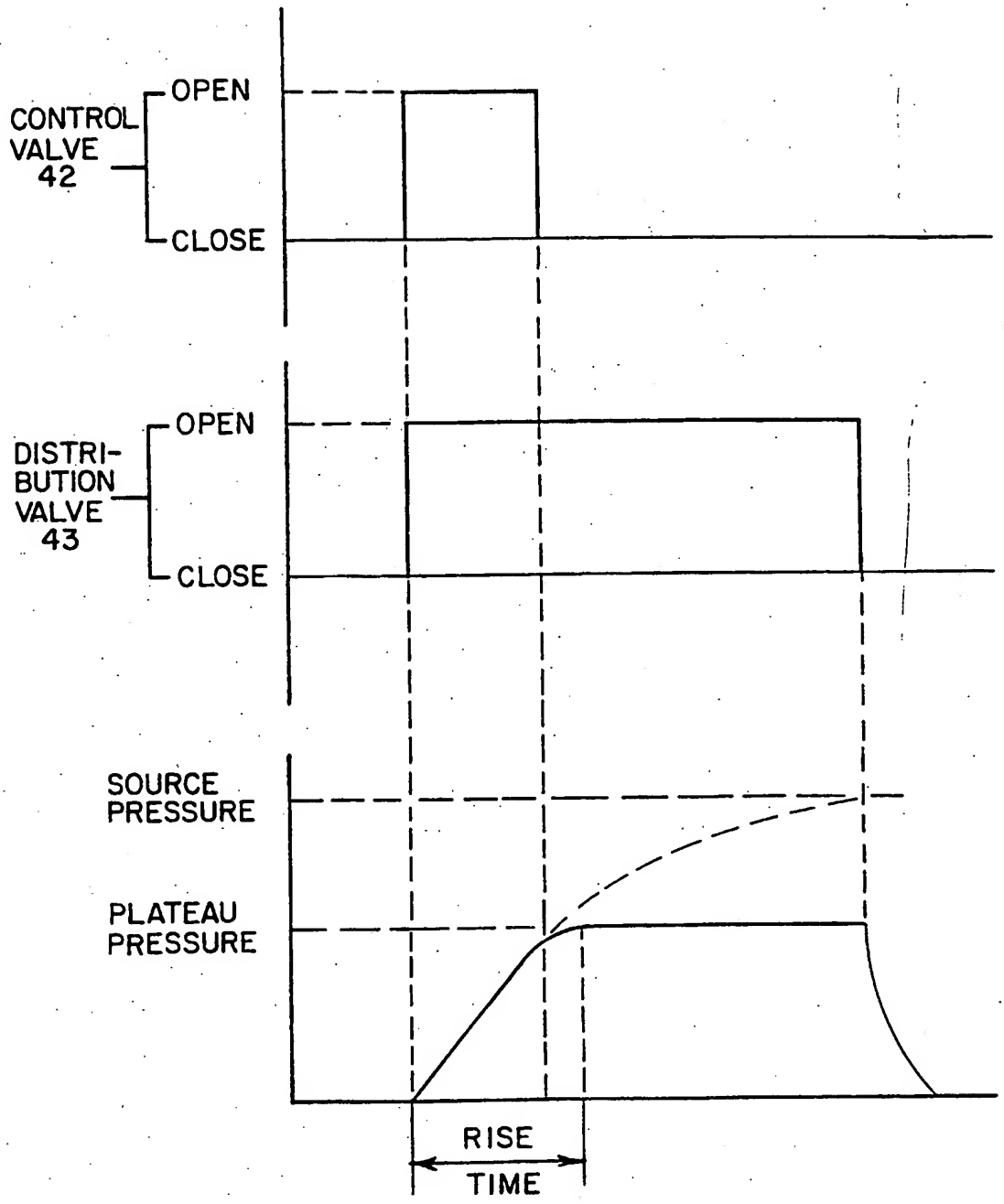


FIG. 4
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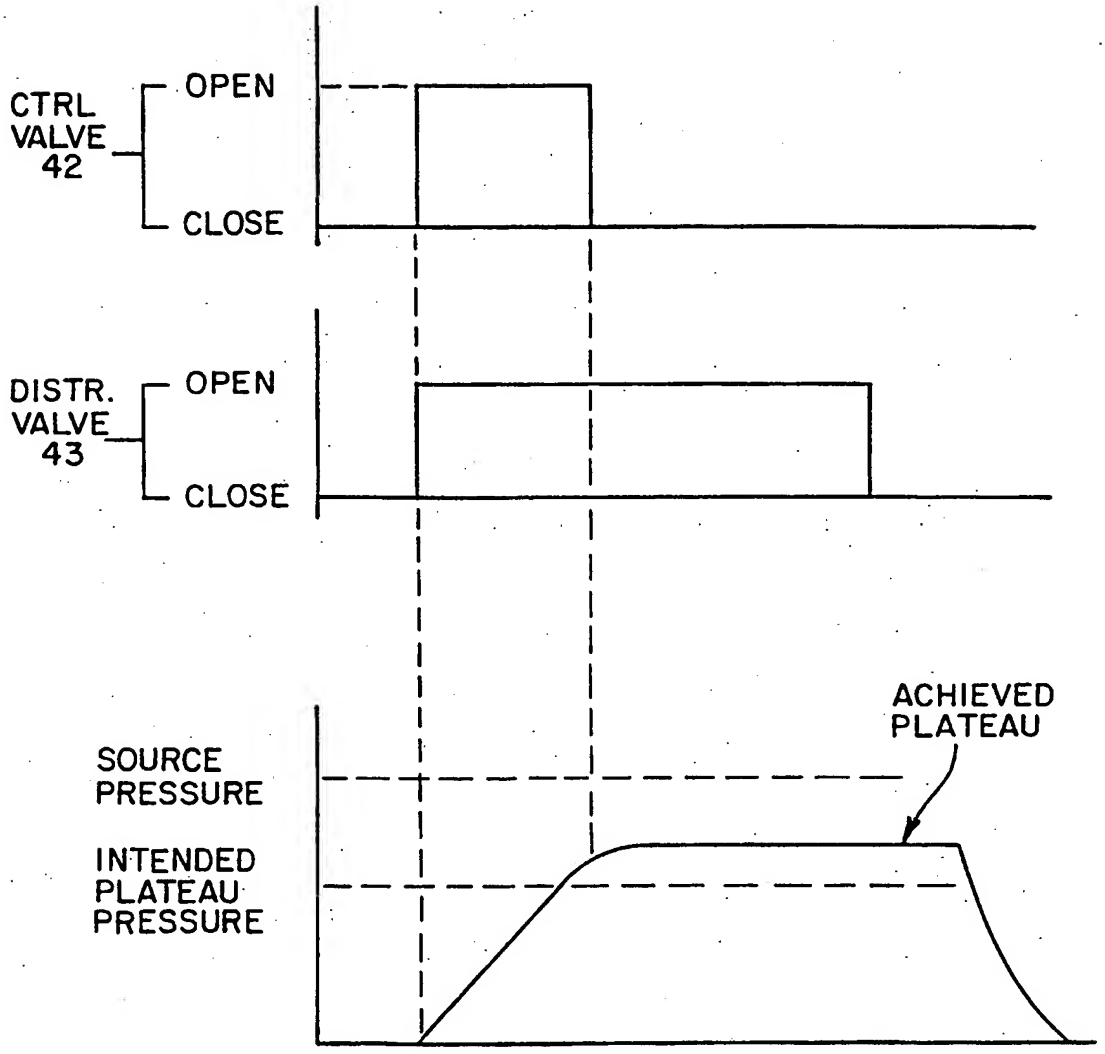
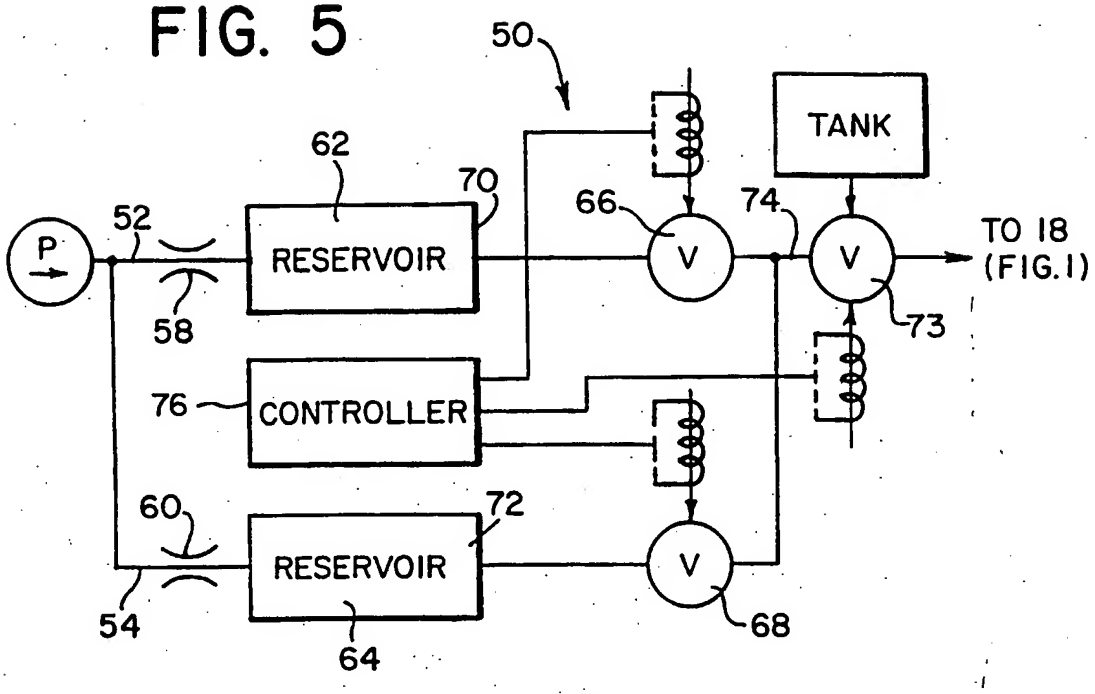


FIG. 5


50
TANK
62
70
66
74
52
P
RESERVOIR
V
V
TO 18
(FIG.1)
58
73
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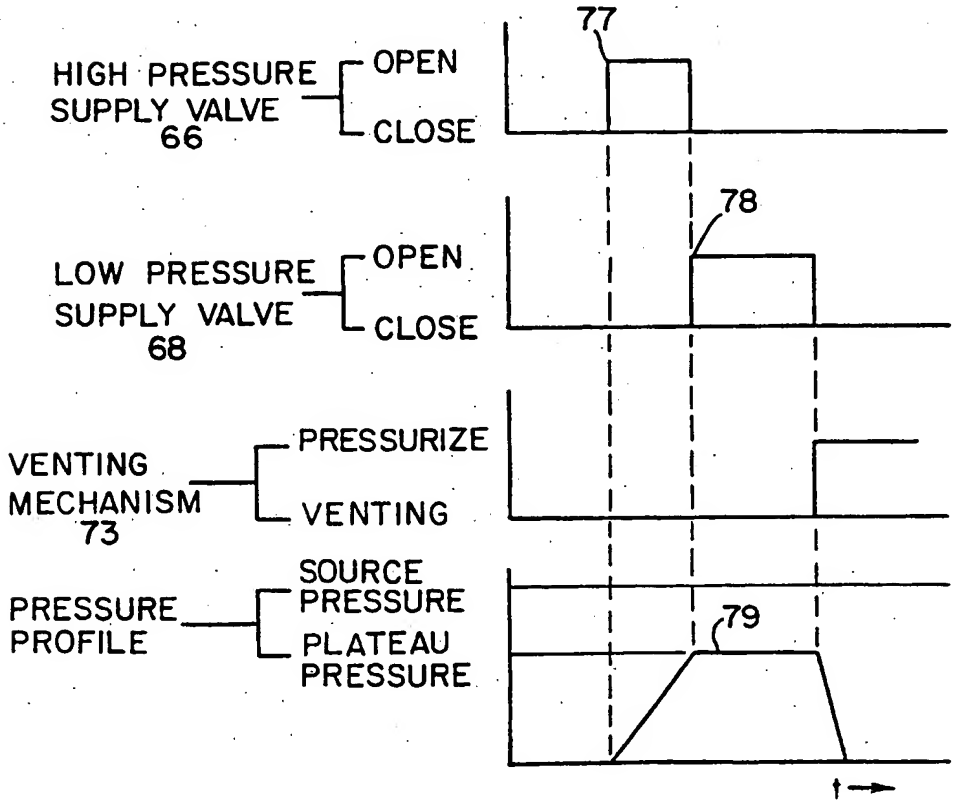
CONTROLLER
60
72
RESERVOIR
V
54
64
68

FIG. 6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VENTING
PRESSURE
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PRESSURE
PLATEAU
PRESSURE
79
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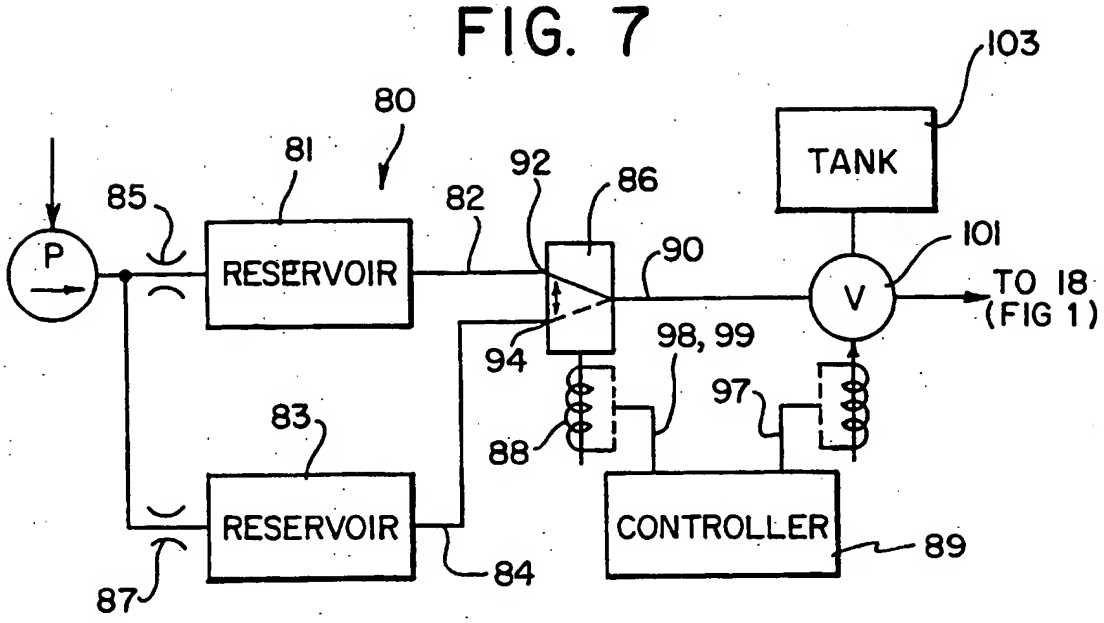
FIG. 7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RESERVOIR
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TO 18
(FIG 1)
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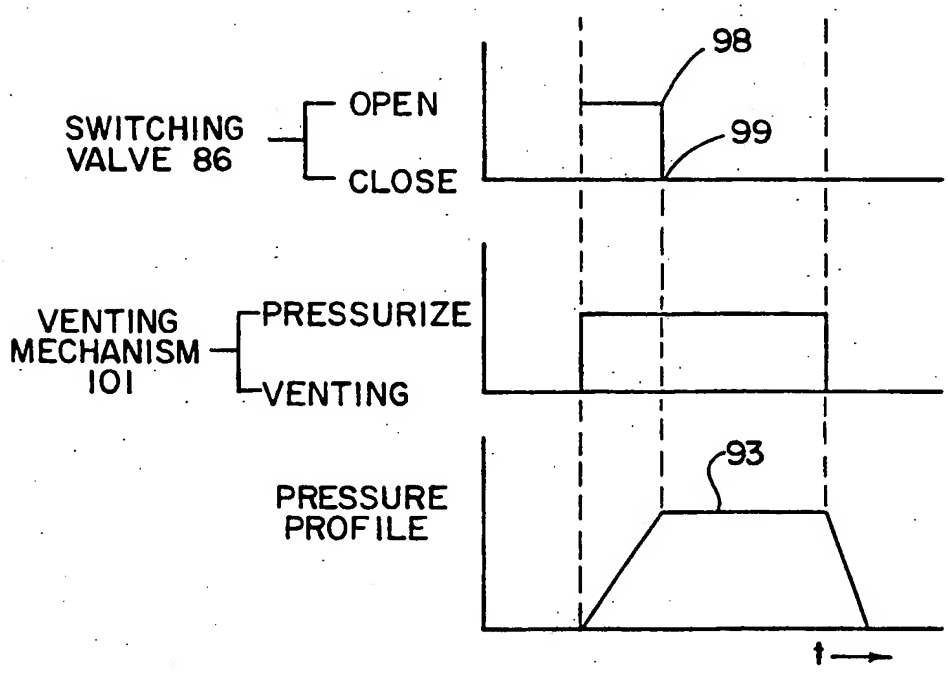
83
88
RESERVOIR
CONTROLLER
89
84
87

FIG. 8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MECHANISM
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PRESSURIZE
VENTING
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PRESSURE
PROFILE
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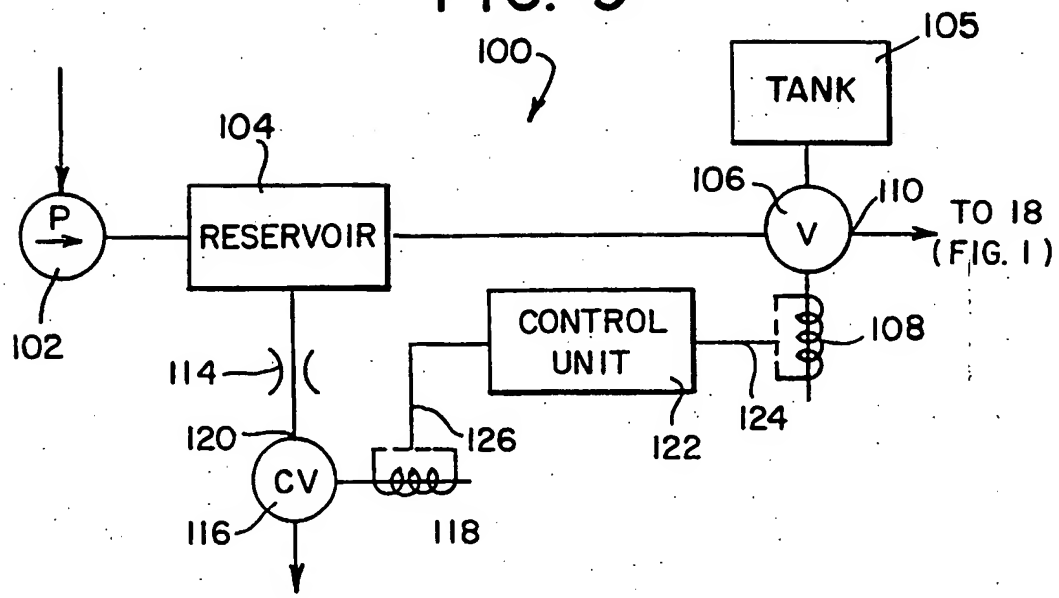
FIG. 9


100
105
TANK
104
106
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TO 18
(FIG. 1)
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RESERVOIR
V
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CONTROL
UNIT
108
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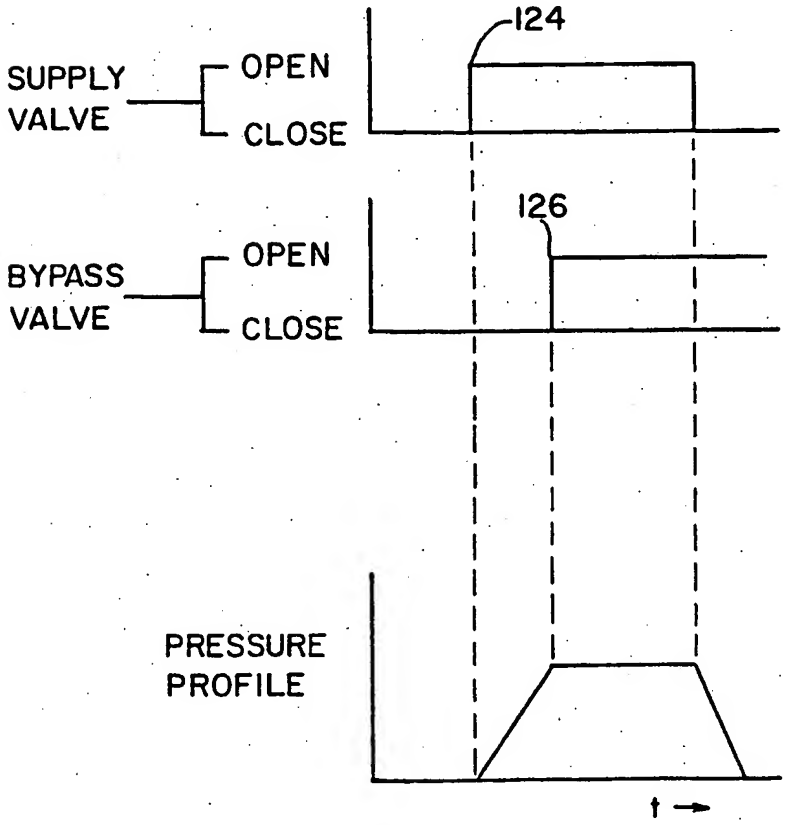
126
122
CV
116
118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BYPASS
VALVE
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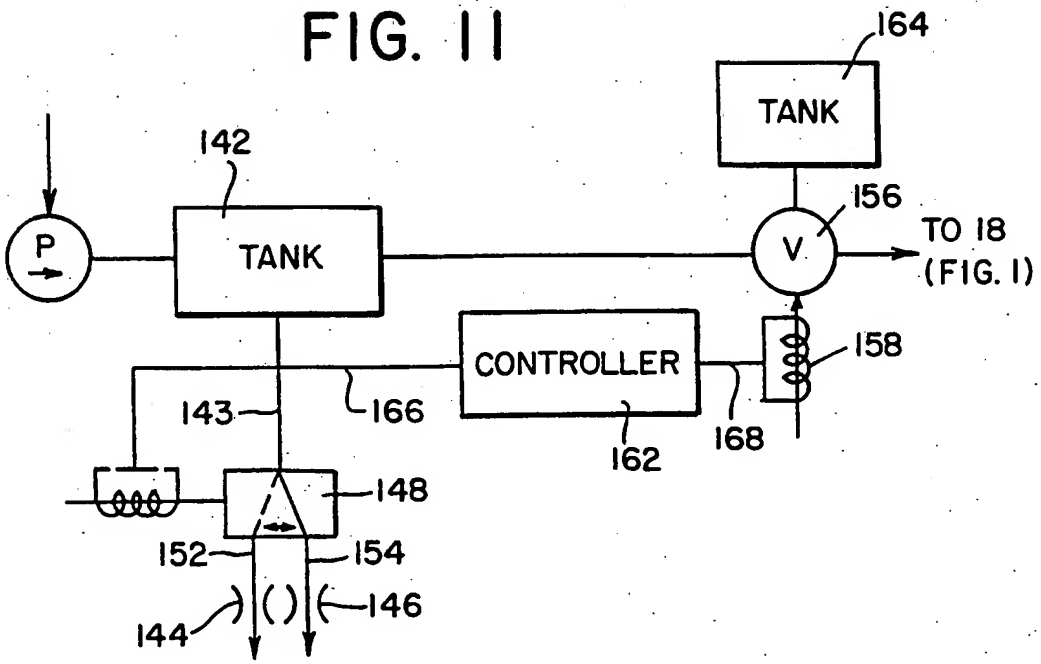
PRESSURE
PROFILE
t

FIG. 10

FIG. 11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142
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P
TANK
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TO 18
(FIG. 1)
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CONTROLLER
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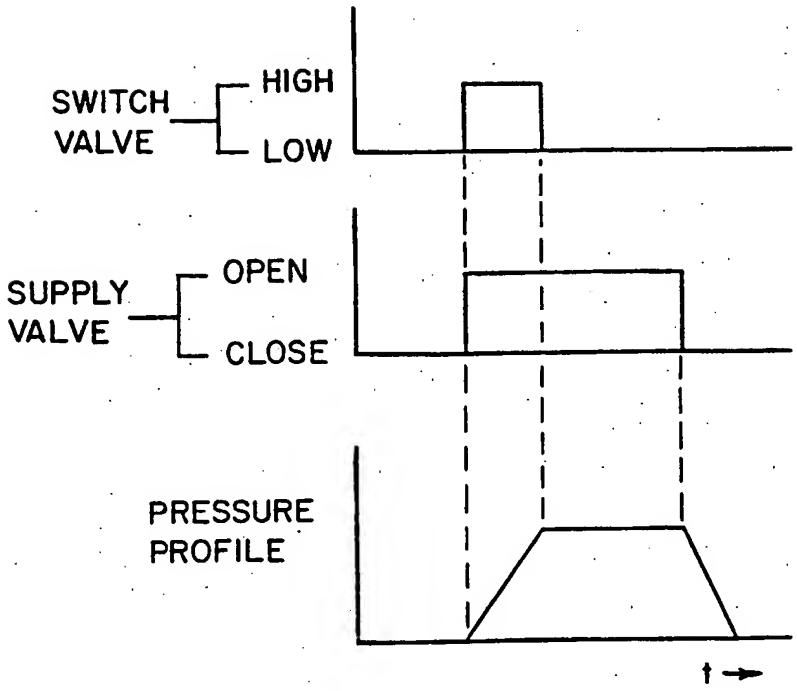
144
146

FIG. 12


SWITCH VALVE
HIGH
LOW
SUPPLY VALVE
OPEN
CLOSE
PRESSURE PROFILE
t

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/06353

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M1/10
US CL :600/016
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/016-018; 606/201-203; 623/003

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,794,910 A (MUSHIKA) 03 January 1989, entire document.	1-31

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 JUNE 1998	Date of mailing of the international search report 06 JUL 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer WILLIAM E. KAMM Telephone No. (703) 308-2994

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